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BMJ Open Protocol for 'Re: CBT Dialysis': a realist evaluation - why, for whom and in what circumstances does cognitive behaviour therapy work for people with depressive symptoms receiving dialysis?

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## **ABSTRACT**

**Introduction** Nearly 40% of adults receiving life-saving dialysis for kidney failure report depressive symptoms. With more than 40 000 Canadians on dialysis, this is a significant health burden. Cognitive behavioural therapy (CBT) has been shown to be effective for treating depressive symptoms: however, it is rarely considered or used for people receiving dialysis. The aim of this realist study is to evaluate and explain how, why, for whom and in what circumstances therapist-quided and remotely delivered CBT works in order to provide equitable mental healthcare to individuals with depressive symptoms receiving dialysis.

Methods and analysis The project will include a realist synthesis, a quantitative cohort study and a realist evaluation. Realist methodology is a theorydriven approach that seeks to explain how generative mechanisms are shaped by contextual features, giving rise to outcome patterns. We will begin by developing an initial programme theory (IPT) from the literature and interviews with CBT therapists to understand how CBT is intended to work and for whom. We will use data from the quantitative cohort study to identify contexts that may shape outcome patterns in CBT for people receiving dialysis. This includes previously collected survey data and data from a longitudinal cohort study, both sourced from people across Canada undergoing dialysis. We will test and refine the IPT using data from a realist evaluation and existing literature. The realist evaluation will involve participants from the quantitative cohort study who received therapist-guided, remotely delivered CBT.

Ethics and dissemination Ethical approvals have been granted. We have planned a wide range of dissemination strategies: journal manuscripts and conference presentations, executive memos for administrators of renal programmes in Canada, an online inventory of resources for depressive symptoms and presentations of findings together with patient partners at all participating

PROSPERO registration number CRD42023476184.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A realist evaluation approach is particularly suited to explore how contextual factors modify the causal mechanisms of the proposed cognitive behavioural therapy intervention to generate the outcomes of interest.
- ⇒ Mixed methods evidence adds methodological strength to this realist evaluation.
- ⇒ An established Community Advisory Committee will co-lead all aspects of the project, ensuring that all elements of design, challenges and chosen mitigation strategies are appropriate to those most impacted by this research.
- ⇒ Due to high illness burden in people undergoing dialysis, there is a risk of attrition, which may impact the robustness of findings.

## INTRODUCTION

Nearly 40% of adults receiving life-saving dialysis for kidney failure report depressive symptoms. Dialysis recipients often experience some of the poorest quality of life among those living with chronic diseases.<sup>2</sup> In Canada, where our study is conducted, over 40 000 individuals receive dialysis.<sup>3</sup> However, despite the high prevalence of sustained depressive symptoms in this population, <sup>1</sup> 4-7 mental health concerns remain inadequately addressed and undertreated,<sup>5 8 9</sup> posing a significant health burden.

Clinicians are hesitant to prescribe antidepressants to people undergoing dialysis due to inconclusive evidence regarding their effectiveness, 10 kidney function impacting effectiveness, pill burden, polypharmacy and medication contraindications.<sup>5</sup> 8 10 11 Additionally, people on dialysis may be reluctant to take antidepressants because of side effects, drug interactions and stigma.<sup>5</sup> Effective



non-pharmacological treatment would be preferable for this population. <sup>10</sup> In response, dialysis programmes and providers are poised to develop and integrate psychosocial mental health strategies into the standard of care for people undergoing dialysis.

Cognitive behavioural therapy (CBT) is a non-pharmacological, psychosocial intervention that has been shown to be effective for treating depression. 12-14 It can be delivered in various formats, including individual or group therapy, remotely via telephone or video call, by a therapist or as self-help, all of which have demonstrated effectiveness. 15 The Canadian Agency for Drugs and Technologies in Health recommends internet-delivered CBT as a cost-effective solution for reducing mild to moderate depressive symptoms and improving quality of life. 16 For people receiving dialysis, who are already living with high treatment burden and declining health outcomes, 17-22 therapist-guided and remotely delivered CBT offers accessible mental healthcare.

A number of systematic reviews and meta-analyses indicate that CBT has the potential to reduce depressive symptoms in people receiving dialysis. 23-28 However, this evidence is based on studies conducted under controlled conditions; it does not explain how and why CBT benefits individuals undergoing dialysis, nor does it identify who benefits from it and who does not. CBT is a complex intervention that unfolds over an extended period, requiring numerous decisions from participants about whether and how to engage with it. Additionally, CBT is multifaceted, employing various therapeutic techniques that are typically tailored to the individual's specific condition. While key CBT strategies, such as cognitive and behavioural interventions, <sup>29–31</sup> are considered vital for clinical improvement, the mediating role of cognitive change remains controversial, as does the process by which change occurs in CBT. 30 32-36 We also lack insights into how various contexts, such as depressive symptom trajectories, health-related variables and sociodemographic factors affect CBT outcomes in dialysis care. 37 38 Attending therapy sessions and engaging in CBT activities can be challenging for people on dialysis who often experience concurrent health issues and high treatment burden. Further, we do not yet understand how CBT may influence a change in the meaning that a person may bring to self-evaluation of depression, also known as response shift. 39 40

A mixed methods realist evaluation approach is ideal for generating evidence with 'explanatory power' that can move the needle on this unaddressed gap in dialysis care. Realist evaluation is a theory-driven, explanatory approach rooted in a realist philosophy of science and has been recommended for use in evaluating complex interventions. Rather than seeking to answer the question of whether a programme works, it aims to understand the causal mechanisms of how and why a programme works and how these causal mechanisms are modified by context. Hence, our aim is not to determine the 'average effect' of CBT for people receiving dialysis but

to investigate the mechanisms underlying its effectiveness and to identify the specific contexts in which these benefits are realised. Specifically, we will develop, test and refine a programme theory to provide concrete guidance to shepherd policy decisions towards the optimal integration and sustainability of CBT into dialysis care.

# METHODS Study aims

Our overarching goal in this realist study is to develop a programme theory that explains how, why, for whom and in what circumstances therapist-guided and remotely delivered CBT can reduce depressive symptoms for individuals receiving dialysis to provide equitable mental healthcare to this population.

## **Research questions**

Programme theory development will be guided by the following research questions (RQs):

RQ1: How is CBT intended to work?

RQ2: What are the different types of depressive symptom trajectories, as well as related patient-reported outcomes, and capacities to engage with CBT including social determinants of health (SDOH), healthcare interventions and health-related variables for people receiving dialysis?

RQ3: How does CBT work to improve depressive symptoms for people receiving dialysis?

RQ4: Why, for whom, and in what circumstances does CBT work for people receiving dialysis with depressive symptoms?

## Study design

RQ1 and RQ4 will be addressed by a realist synthesis. RQ2 will be addressed by previously collected survey data, 45 previously collected data from a longitudinal quantitative cohort study<sup>46</sup> and supplemented with primary data collection. RQ3 will be addressed by a realist evaluation. An initial programme theory (IPT) will first be developed in step 1 of our realist synthesis and with data from the quantitative cohort study, aiming to explain how CBT may reduce depressive symptoms in individuals receiving dialysis. This IPT will identify the underlying mechanisms through which CBT may reduce depressive symptoms in individuals receiving dialysis, as well as the contextual features that may influence these mechanisms. This IPT will then be tested and refined in the realist evaluation and steps 2–5 of the realist synthesis. We chose a realist evaluation approach because it seeks to understand how causal mechanisms are shaped and constrained by context to generate the outcomes of interest in complex interventions 46-48 and is, therefore, suitable to answer our RQs. For definitions of context, mechanism and outcome, see table 1. Using mixed methods evidence within this realist evaluation, we will draw on data from our quantitative cohort study and the realist synthesis to identify contexts, survey data from the realist evaluation



Table 1 Definitions of context, mechanism and outcome	
Term	Definition
Context	Context encompasses the conditions and circumstances under which mechanisms become active. This includes a person's characteristics and capacities, programme properties, interpersonal relations as well as the broader social, economic, institutional and cultural norms and settings. In realist evaluation, contexts cannot be understood independently of a mechanism; it is the special condition that shapes and modifies a particular mechanism that generates the outcome of interest.
Mechanism	In realist evaluation, mechanisms are the underlying forces that shape outcomes. Mechanisms are not necessarily identical to those proposed by the 'official' programme theory. A programme offers resources, and how these are used depends on an individual's choices and their capacities to act on these choices. Moreover, mechanisms are context- sensitive, meaning that they are activated only in specific contexts. In summary, mechanisms in this study are understood as an individual's responses to the resources provided by CBT, leading to various outcomes.
Outcome	Outcomes result from the interaction between contexts and mechanisms. They can range from a person's involvement with CBT to various mental health and well-being outcomes and behavioural changes, and they may include intended and non-intended, proximal and distal outcomes.
*Informed by Pawson <i>et al.</i> <sup>51</sup> and Wong <i>et al.</i> <sup>98</sup> CBT, cognitive behavioural therapy.	

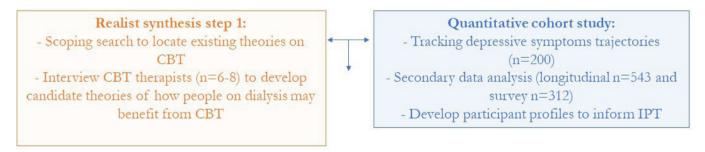
to measure outcomes and qualitative data from both the realist evaluation and the realist synthesis to identify the causal mechanisms linking contexts to outcomes. Mixed methods evidence will ultimately be synthesised to refine the IPT into an equitable and evidence-based functional programme theory explaining how, why, for whom and under what circumstances CBT 'works'. Our study started in March 2023 and will continue until the end of February 2026. For an overview of the study design, see figure 1, as

well as further details about all data collection activities in online supplemental file 1.

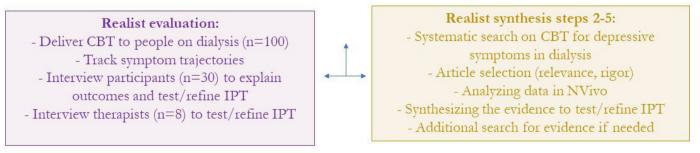
## **Realist synthesis**

Our realist synthesis follows Pawson's five steps of realist synthesis, <sup>43</sup> moving iteratively from (1) mapping the territory and formulising the model and hypotheses to be tested, (2) searching for primary studies, (3) quality appraisal and (4) data extraction to (5) data synthesis.

# DEVELOP Initial Programme Theory (IPT)



TEST & REFINE Programme Theory: Why, how, for whom, in what circumstances does CBT work?



**Figure 1** Study design. RQ2 Secondary data analysis: longitudinal data refer to the previously collected cohort data from our 'ePRO Kidney' study. Survey data refer to the cross-sectional data from a survey sent to Albertans receiving dialysis about willingness to receive mental health supports, including CBT. <sup>45 46</sup> CBT, cognitive behavioural therapy; RQ, research question.



## Step 1: develop IPT

As a first step, we will develop an IPT to explain how CBT is intended to work and how this may apply to people living with dialysis treatment. To identify theories and evidence that facilitate understanding of how and why CBT works for different populations, a broad and scoping search will be undertaken. Together with an experienced health sciences librarian (MK) familiar with systematic searching and realist review methodology, we have developed a search strategy to be used for OVID EMBASE and Scopus. These databases were selected for their comprehensive journal index. Search terms were derived from the intervention of interest, CBT and refined to theory-based literature. Results were limited to books and book chapters, umbrella reviews, meta-analyses and Cochrane systematic reviews. In addition to conducting searches of library databases, we will use Google to search the websites of psychological associations, psychotherapy and counselling institutions in Canada, the USA, the UK, Australia, New Zealand and the European Federation. See online supplemental file 2 for our full search strategies.

From our first search, we will hand-pick a selection of documents to gain an overview of the key ideas and assumptions underlying CBT. We will then screen all remaining articles for additional theories to (1) add to our understanding of how CBT works in general and/or (2) help us build theories of why and for whom CBT 'works' in dialysis care. We will add documents that we identify through citation tracking and consider relevant for theory building. Screening will include documents on adults in general and adults with depression, fatigue, general long-term physical health issues, general incurable diseases, comorbidities and mental health issues related to dialysis. Literature on people with specific mental health needs, such as psychosis, addiction or specific phobias will be excluded. We will further only include literature on individual CBT, either delivered in-person or remotely via video call or telephone and exclude group CBT and self-help formats as well as mindfulness- and acceptance-based CBT approaches. The reason is that we think CBT for specific mental health needs, group CBT, self-help formats and mindfulness- and acceptancebased approaches may involve different mechanisms than individual standard CBT for depressive symptoms and longterm illnesses. For more details, see 49.

For IPT development, we will conduct semi-structured, in-depth interviews with CBT therapists (n=6–8). Therapists will be recruited with snowball sampling through one team member (DC) and team collaborators in Canada and the USA. We will invite therapists who have experience in developing or providing CBT to adults in general and/or to adults receiving dialysis. The purpose of these interviews is theory gleaning<sup>50</sup>; that is, we want to elicit from practitioners candidate theories of how and for whom CBT 'works' in dialysis care (see online supplemental file 3a for interview guide).

From our scoping literature search and the interviews, we will build a first set of context-mechanism-outcome

configurations (CMOCs). CMOCs are a heuristic in realist research used to express theories of how contexts are expected to shape or modify mechanisms (ie, causal, often unseen, non-linear forces) to generate outcomes. <sup>5152</sup> CMOCs will be written as 'if...then...because' hypotheses. Retroduction may be used to identify mechanisms that explain outcome patterns. Retroduction is a form of reasoning used in realist research to uncover underlying causal powers that could be contributing to the observed outcomes. <sup>53</sup> CMOC development will be performed by one team member (KM), and the results will be regularly shared and discussed within the team (KS-M, JG and LSHL). This set of CMOCs will contribute to the formulation of the IPT.

## Steps 2–5: test and refine IPT Search

Next, we will conduct a systematic search to identify the literature on CBT for people with depressive symptoms receiving dialysis. Together with the same health sciences librarian (MK) as in step 1, we have conducted a preliminary systematic search in February 2023 (see online supplemental file 2b for the full search strategy). Aligned with the quality standards of realist synthesis, <sup>54</sup> the systematic search may be adapted iteratively to test and refine specific sections of the programme theory. It may extend beyond the boundaries of CBT to situations where similar mechanisms are likely involved and include the existing theories from psychology or sociology to help explain the mechanisms of our programme theory.

## Selection and appraisal of documents

Titles and abstracts will have 10% double screening; full texts will be double screened. We will apply the same inclusion/exclusion criteria as in step 1. In accordance with Realist And Meta-narrative Evidence Syntheses -Evolving Standards (RAMESES) realist synthesis methodology,<sup>54</sup> quality assessment will focus on two main criteria: (1) whether the document contributes to theory development, testing or refinement (relevance) and (2) whether the methods used to generate the relevant data are credible and trustworthy (rigour). Study quality will be further assessed using McGill Mixed Methods Appraisal Tool,<sup>52</sup> but studies will not be excluded on the basis of scores because relevance is determined by the contribution of data towards testing the programme theory. Saturation is guided by values of appropriateness, adequacy and analytic redundancy for theory development.

## Data analysis and synthesis

Included documents will be coded in NVivo. The same processes as outlined in step 1 for both coding and a retroductive approach to analysis will be followed. Two team members will extract the data; a random selection of articles will be independently coded by KS-M. The team will discuss and resolve extraction differences. During synthesis, we will ask, 'What does this evidence suggest about this aspect of our theory? Does it support it? Does it



disprove it? Does it suggest an amendment to it?' We will use analytical processes as outlined in our PROSPERO protocol.<sup>49</sup> To move from analysis to synthesis, formal theories may help with 'sense making'. Examples include the theories of behaviour change, communication or complexity.

## Quantitative cohort study of depressive symptoms

The goal of this quantitative cohort study is to describe the different types of depressive symptom trajectories, as well as related patient-reported outcomes and capacities to engage with CBT, including SDOH, healthcare interventions and health-related variables for individuals from across Canada who are receiving dialysis. In other words, we will identify contexts that may shape outcome patterns in CBT for that population. For that purpose, we will conduct secondary data analysis of the team's previously collected data with people receiving dialysis and their mental health. <sup>45</sup> <sup>46</sup> To address shortcomings of these data, we will collect primary data through a longitudinal cohort study of individuals (n=200) from across Canada who are receiving dialysis.

## Data collection

Participants will be recruited across Canada. To be eligible for the study, individuals need to receive ongoing dialysis, either chronic home dialysis (haemodialysis and peritoneal dialysis) or in-centre (hospital or community) haemodialysis. They further need to be adult (the age may vary across provinces) and able to participate in English. Participants will be recruited nationally through Kidney Foundation of Canada posting, Kidney-Link, Can-SOLVE CKD (LinkedIn, Facebook, Twitter and newsletters) and locally at select partner sites in Alberta and British Columbia through mailing invitation letters, posters in dialysis centres, consent-to-contact and in-person recruitment. Consent will be written or verbal. Data will be collected online and by phone. The reason for including data collection via phone is that we want to obtain robust data from diverse people receiving dialysis who are often older adults and often prefer paper and call-based surveys over online survey completion. We are not screening for depressive symptoms as an inclusion criterion because we want to understand the trajectories of all participants. Baseline data collection is informed by Canada's genderbased analysis plus (GBA+) framework<sup>53</sup> and includes SDOH data (eg, sex, gender, age, race/ethnicity, housing and financial strain), information about healthcare interventions (eg, standard care) and health-related variables (eg, comorbidities, social support, medications and healthcare use). Each individual will be followed for 6 months, where we will collect data on depressive symptoms using the Patient Health Questionnaire 9-item scale <sup>55</sup> (PHQ-9; biweekly) and related patient-reported outcomes using the Kidney Disease Quality of Life 36-item scale<sup>56</sup> 57 (KDQOL-36; baseline, 3 and 6 months), the Generalised Anxiety Disorder seven-item scale<sup>58</sup> (biweekly) and The McGill Quality of Life Single-Item Scale (biweekly).<sup>59</sup>

Participants will further be invited to describe their emotional well-being or depressive symptoms in an openended question (biweekly). We will measure participants' self-efficacy at one time-point using the Generalised Self-Efficacy scale.<sup>60</sup> Finally, participants will be asked if they would like to be informed about receiving CBT and to provide reasons, in an open-ended question, for their lack of interest in CBT. To further inform the IPT, we will incorporate previously collected longitudinal cohort data from our 'ePRO Kidney' study 46 and cross-sectional data from a survey sent to Albertans receiving dialysis about willingness to receive mental health supports, including CBT. 45 These data include additional measures of mental health, chronic illness self-management and preferences for mental health therapies that will allow targeted analyses to inform IPT development in relation to participants' capacity to engage with CBT.

## Statistical analysis

The analyses for RQ2 are exploratory and predominantly descriptive. We will use individual growth models to (1) describe and visualise depression trajectories based on (PHQ-9) scores and (2) identify contextual factors (including SDOH, healthcare interventions and other health-related variables) that explain individual-level variability in depressive symptoms. Given the exploratory and descriptive nature of these analyses, a diverse sample of 200 will be sufficient, combined with the above noted data for secondary supplemental analyses. The possibility of response shift (ie, a change in the meaning of one's self-evaluation of depressive symptoms) will be explored using structured equation modelling. 61 62

## **Realist evaluation**

Our realist evaluation addresses RQ3, which examines how CBT works to improve depressive symptoms for people living with dialysis treatment. We will deliver ten 45-min CBT sessions over 12 weeks to people with depressive symptoms receiving dialysis. Sessions will be delivered remotely via live audio or video over the internet by an allied health therapist (eg, a nurse or a social worker). Therapists will be trained by DC to follow a manual that was developed by DC in a pilot study.<sup>37</sup> The CBT protocol has been tested in a multicentre trial delivered as face-to-face therapy to individuals receiving haemodialysis.<sup>38</sup> The manual includes standard CBT components, such as psychoeducation, behaviour activation, cognitive restructuring and health behaviour modification, adapted for people living with dialysis treatment. Adaptations include psychoeducation on depressive symptoms in people undergoing dialysis, anxiety management, as well as teachings and reflections on sleep hygiene and healthy living. Furthermore, examples in the participant handbook have been adapted to match the specific situations of people living with dialysis treatment. (For an overview of the CBT programme, see online supplemental file 4).



## Data collection

All participants involved in our quantitative cohort study will be invited to receive CBT. Anyone who expresses interest in receiving CBT for depressive symptoms will be eligible to participate. We expect to recruit 100 participants. Allied health research staff will talk to each potential participant for recruitment and exclude anyone who is medically unstable; receiving temporary dialysis for acute conditions; living with schizophrenia, psychosis or bipolar disorder; planning to stop dialysis; living with dementia or severe cognitive impairment; unable to provide informed written or verbal consent; or at high risk of suicide. The same survey variables will be collected from these participants as in the previous quantitative cohort study, as well as additional surveys needed to test and refine the IPT. Given the emergent and iterative nature of realist evaluation methodology,<sup>63</sup> data collection and analysis may be adjusted based on the evolving programme theories identified during the realist synthesis and evaluation. In addition, participants will be asked to describe their CBT experiences narratively via open-ended questions. We will invite participants across sites to focus groups or interviews immediately after completing CBT. In these interviews and focus groups, we will present participants with their symptom trajectories and ask them to help interpret their results. We will use realist interview techniques<sup>50</sup> to explore how participants benefitted (or did not benefit) from CBT. In addition, we will present them parts of our IPT and ask for their experience and feedback. We will also invite all therapists to a semi-structured interview to test, refine and consolidate our IPT (see online supplemental file 3 for all interview guides).

# Data analysis and synthesis

We will employ mixed methods analyses guided by a realist approach,  $^{64-70}$  which involves iteratively implementing different analytic approaches using diverse data sources to test and refine the programme theory. Qualitative data analysis will follow the same heuristic analytic approach of coding and analysis of the CMOC as outlined above for our realist synthesis. <sup>69</sup> <sup>71</sup> <sup>72</sup> We will use established methods to ensure rigour and trustworthiness, including credibility (consultation with interest holders and negative case analysis), confirmability (audit trails) and transferability (CBT settings). 73 74 Person-centred approaches to statistical analysis<sup>75</sup> will be applied to describe individual depressive symptom trajectories and explanatory variables with the goal of understanding why some individuals improve differently than others. Through retroductive reasoning, we will weave together results from qualitative and quantitative analyses to hone the articulation of CMOCs that explain how, why, for whom and in what circumstances CBT works.

## Patient and public involvement

Patients and clinicians first alerted us to the need for this study. Through our research, we identified that depressive symptoms experienced by Canadians receiving dialysis are not routinely assessed and inadequately addressed.  $^{\!\!\!4\,46\,76-80}$ This was confirmed in our realist synthesis on patientreported outcome use in kidney care<sup>81</sup> and by some of our Community Advisory Committee members in a kidney patient-led study on mental wellness, who state 'the most glaring gap in care is the lack of psychosocial support available to patients' (p.3). These Advisors are a part of our established Community Advisory Committee, involved since project conception. The Community Advisory Committee is co-chaired by a patient partner (LL) and includes ten members: people with lived experience of dialysis, relatives of those receiving dialysis, recipients of kidney transplants and community members with personal connections to dialysis. The Community Advisory Committee meets monthly; they reviewed the initial proposal focus, research questions, design, recruitment and dissemination strategies. The proposed work will be led throughout in partnership with this established Community Advisory Committee.

## **ETHICS AND DISSEMINATION**

Ethical approval has been granted for conducting interviews with CBT therapists as a part of IPT development from the University of Alberta (ID Pro00129407) and Trinity Western University (ID 23EA03). For our quantitative cohort study, we obtained ethical approval from the University of Alberta (ID Pro00129407); the University of Calgary (ID pSite-23–0034); Trinity Western University (23EA03); the University of British Columbia (ID H23-01464); the Northern Alberta Clinical Trials and Research Centre (ID 66059); Alberta Health Services (ID 23EA03); Fraser Health (ID H23-01464); Interior Health (ID 2023-24-029-H); Vancouver Coastal Health (ID H23-01464) and Island Health (ID 102785–140692). We will seek ethical approval for our realist evaluation in spring 2024.

Our programme theory will be presented to decisionmakers in virtual workshops involving discussion, feedback, revisions and confirmation. To attend to rigour, presentations will be tailored to the audience, depending on whether it is patient-, clinician- or researcher-focused. We further intend to report our programme theory in accordance with RAMESES II reporting standards. 5468 End of grant reporting will follow integrated knowledge translation (KT)<sup>82</sup> and gender-transformative KT<sup>83</sup> approaches with guidance from the Community Advisory Committee and interest holders. KT products will include: (1) executive memos for administrators of renal programmes in Canada explaining how, why, for whom and in what circumstances CBT works; (2) an online inventory of resources for depressive symptoms (eg, local crisis phone numbers, peer support, websites and modules posted on www.healthygol.com/kidney), developed throughout the project with Community Advisory Committee members and site collaborators and (3) presentations (with patient partners) of findings at all participating sites. Dialysis programmes are keenly interested in exploring



integration and sustainability of CBT. The GBA+framework<sup>53</sup> will ensure that gender, sex and other identities are woven into the equitable programme theory, and it will inform gender-transformative KT strategies towards dissemination.

## **IMPLICATIONS**

The costs, both personal and to the healthcare system, are substantial. People with depressive symptoms receiving dialysis have lower quality of life, 84-86 lower odds of transplantation, <sup>87</sup> increased mortality, <sup>88</sup> increased risk for hospitalisation, <sup>89 90</sup> more frequent emergency department visits<sup>91</sup> and longer hospital stays<sup>92</sup> than other people receiving dialysis. There is currently no form of psychosocial intervention available as standard of care at dialysis centres in Canada. Our work will fill this gap while promoting equitable, people-centred mental healthcare in alignment with global priorities. 93–96 We will engage patients and interest holders to not only bridge this gap in dialysis care previously ignored for decades 497 but also support a key culture change towards people-centred care by answering decision-makers' question of 'why, for whom and in what circumstances does CBT work?' In so doing, we will shepherd policy for optimal integration and sustainability of CBT.

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