# Mind the Gap: Addressing Mental Health Care Gaps for Canadians Receiving Facility-Based Hemodialysis

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**September, 2025**

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**Can-SOLVE 2.0 Theme 3.1: Research Protocol for Ethics Application**

*Short title*: Mind the Gap: Can-SOLVE CKD 2.0 Theme 3.1

*Long title*: Mind the Gap: Addressing Mental Health Care Gaps for Canadians Receiving Facility-Based Hemodialysis

## BACKGROUND

Mental health concerns for people receiving hemodialysis are disproportionately high and undertreated.[1-9] Isolation, fear of severe illness and limited access to healthcare services during the COVID-19 pandemic has contributed to an increase in mental health distress.[10-27] As one patient explained, "*Mental health can deteriorate in a split second and linger long after. If a patient has no one to talk to, it can become worse than the disease*."

*Triple I: Improving Information, Interactions and Individualization for people receiving in-centre Hemodialysis*, a multi-centre mixed methods Can-SOLVE CKD Network project, identified the Top 10 Challenges to in-centre hemodialysis care. Importantly, we found that people receiving hemodialysis view addressing access to mental health care as a top priority.[28] Specifically, coping with hemodialysis and an individualized, accessible, culturally-sensitive approach were identified as key mental health care gaps. Although potential solutions to these gaps exist,[28,29] their feasibility and efficacy is unknown.

The prevalence of self-reported mental health symptoms for adults receiving hemodialysis is 2-5 times higher than the general population[30,31] and associated with adverse outcomes.[32] Despite increasing needs for mental health care due to the additional pressures from the COVID-19 pandemic, current mental health supports for individuals receiving hemodialysis are inadequate. [3,4,33] Hemodialysis clinicians acknowledge the gaps in mental health care in hemodialysis need to be addressed, but lack training and resources to provide such care.[3,4,33]

As a part of the Can-SOLVE CKD Network of researchers, in which patient engagement is a guiding principle of all the research projects, patient partners form an integral part of our diverse research team and will contribute to each stage of the project. Through our work with the Triple I project we have expertise in authentic patient engagement and have established relationships and collaborations with Indigenous stakeholders. We will use a *gender-based analysis plus* (GBA+) approach that will consider sex, gender, ethnicity, race and age in order to be sensitive to the effect of identity factors on mental health.[34] Such factors can account for differences in the overall burden of mental health, preferences for and response to treatment and willingness and ability to access mental health resources.

Our research approach will ensure the development of individualized, accessible and culturally-sensitive mental health supports and implementation strategies. Specifically, systemic racism and historically-abusive institutional practices have resulted in inter-generational trauma and mistrust of the healthcare system and have directly impacted the health of Indigenous peoples.[35,36] In an effort to bridge the gaps towards reconciliation, this research aims to make mental health services available, appropriate and accessible, potentially reducing mental health inequities faced by Indigenous individuals receiving HD in Manitoba.

## AIMS

In partnership with people living with kidney disease, clinicians, healthcare providers and decision makers, the overall goal of this program of study is to identify and address priorities for improving mental health care for individuals receiving hemodialysis. By mobilizing research-generated-knowledge from Can-SOLVE 1.0 (Triple I) and engaging patient partners at all stages, from conceptualization to knowledge translation (KT) of results, this project will optimize person-centred[37-39] mental health care, leading to improvements in mental health, patient experience and quality of care in hemodialysis.

***Aim 1*:** to identify and catalogue the existing mental health resources available to individuals receiving hemodialysis in Canada; including identifying and cataloguing those resources that are specifically targeted to Indigenous individuals receiving hemodialysis in Manitoba.

***Aim 2*:** to identify the top priorities to address in mental health care in hemodialysis and potential innovations (e.g. tools, strategies, models of care) to improve mental health care in people receiving hemodialysis, as identified by multiple stakeholders including, people receiving hemodialysis/caregivers and healthcare providers.

***Aim 3a*:** Using information obtained in the first TWO study aims, we will design an evidence-based mental health support strategy tailored for Canadians receiving hemodialysis, and develop implementation and evaluation plans to test this strategy.

***Aim 3b*:** Implement and evaluate the Alberta pathway for mental health for individuals receiving hemodialysis.

## METHODS

This multicentre, mixed methods project engages patient partners at every stage; from establishing methodology for the environmental scan and qualitative data collection to devising and testing implementation strategies.[40] Our iKT approach follows the Knowledge-to-Action-Framework,[41,42] working towards research-driven implementation (see Appendix A for Project Framework).

**Aim 1: Environmental scan of mental health resources available for people receiving hemodialysis.**

We will perform a cross-Canada environmental scan to develop a national online inventory of resources for mental health issues. Some resources included may be specific to people receiving hemodialysis, but we will include all resources available to the general population as well. Resources will be identified systematically provincially using online Google/Web search for resources, including health agencies and public-facing resources. Once compiled, the resources will be reviewed by patient partners and other stakeholders (caregivers, healthcare providers) for completeness and to identify key care gaps.

In Manitoba, we will engage with First Nations and Metis organizations, (First Nations Health and Social Secretariat of Manitoba; Ongomiizwin – Indigenous Institute of Health and Healing at University of Manitoba; Manitoba Metis Federation), Indigenous patient partners and healthcare providers and Indigenous knowledge keepers to identify existing culturally-sensitive and appropriate mental health resources for Indigenous people to be included in the environmental scan for Manitoba

The provincial mental health resources collected will be compiled and developed into an online accessible resource housed on the Mind the Gap Project website (https://www.mindthegap-ckd.ca) and at https://www.healthyqol.com/kidney.

***STATUS:*** *ENVIRONMENTAL SCAN COMPLETED and is being updated regularly. In Manitoba, efforts to engage Indigenous organizations and individuals continue.*

**Aim 2: Identifying priorities in mental health care for people receiving hemodialysis.** This will be a pan-Canadian qualitative descriptive study[43] to provide a descriptive summary of participant's priorities for addressing mental health care gaps for people receiving hemodialysis as well as their reasons for these suggestions and potential solutions to these priorities. Three sequential components of qualitative data collection will be conducted (1) surveys, (2) priority setting process workshop and, (3) focus groups:

**1) SURVEYS:** ***Identifying priorities for mental health care in people receiving hemodialysis.***

Two similar but distinct open-ended surveys (available electronically through REDCap and in paper-based format) will be conducted across Canada with (A) People receiving hemodialysis/their caregivers and (B) healthcare providers working in hemodialysis. A period of 3 months will be given to complete this exercise. The two versions of the survey will consist of open-ended questions and will be completed anonymously. No IP addresses will be stored. In addition, we will request that all survey respondents provide the following information on the last page of the survey: age (10-year groups), province of residence, gender, ethnicity, profession, role (person living with kidney disease or caregiver of patient/relative, health care provider, other) and how long they (or the person with kidney disease they are associated with) have been on hemodialysis/working in hemodialysis. This information is being collected to determine

whether the population of interest has been captured and whether priorities for mental health are influenced by these factors.

*a. People receiving dialysis/caregivers:* We will contact patients and caregivers for participation in 2 ways. First, we will post a link to the survey on the following websites: Canadian Nephrology Trials Network (CNTN), the Kidney Foundation of Canada, Can-SOLVE CKD, and clinical kidney care program websites across the country. Posters will also be placed in hemodialysis unit waiting rooms across the country to make people attending hemodialysis aware of the survey. We plan for the survey to be available online for 3 months.

To allow for individuals who do not have access to the internet or who prefer to complete hard copy surveys, up to 5 hemodialysis centres across Canada will provide hard copy surveys to the people dialyzing in their unit and invite them to complete the questionnaire (either by paper or online). Currently Edmonton, Winnipeg (Seven Oaks Hospital unit; Health Sciences Centre hemodialysis units and St. Boniface Hospital hemodialysis units) and Halifax will participate and 2 more sites will be identified to ensure that in total surveys are geographically representative across Canada. The survey will provide a letter of information on the first page summarizing the project, explaining that the survey is entirely voluntary and that completion indicates consent. An information poster advertising the survey will be posted in the waiting room of participating hemodialysis centres. Hemodialysis clinic staff will distribute copies to people receiving hemodialysis who are eligible for participation during their dialysis sessions and provide an envelope to ensure anonymity when returning surveys. A study research assistant will be present in the hemodialysis unit to assist individuals with survey completion if necessary. Patient partners, who are partners in research and have lived experience either as a hemodialysis patient themselves or as a caregiver for a loved one, will also be present in the hemodialysis unit to discuss the study and survey with patients and answer any questions they may have. For mental health support, the information letter will contain instructions on how to receive such support, including but not limited to (1) requesting for a renal social worker, (2) and providing a link (i.e. https://healthyqol.com/kidney) to a website with a catalogue of available mental health resources specific to their province of residence. We aim to recruit 60-80 patients/caregivers including 25% Indigenous patients/caregivers (purposive recruitment) to complete the survey in Winnipeg (Total 300 across the country). Eligible patients will be currently treated with maintenance hemodialysis, be aged 18 years or older, and be able to communicate in English.

*b. Healthcare providers:* We aim to recruit 40-50 healthcare providers from Manitoba with HD expertise (total 200 overall including all sites). A study staff member will distribute an email to participating hemodialysis unit managers which will include a study information letter and a link to the online survey and will ask the managers to forward email to all hemodialysis unit staff. To ensure we capture our population of interest, participants will also be invited using a purposive (supplemented by snowball) sampling approach. Key stakeholders in nephrology from the Manitoba Renal Program will be asked to recommend nephrologists, nurses, allied health professionals and policy makers who have HD expertise to participate in this study. Contact information will be identified from publicly available sources.

**Survey A for people receiving hemodialysis/their caregivers** will be further developed and refined using an iterative process of action and reflection from piloting for face and content validity in collaboration with our Mind the Gap project patient partners. A second pilot will be performed with the first 10 patients who complete the survey in Winnipeg after which survey revision for readability and comprehension may occur.

At the Winnipeg site, the study Indigenous patient partner sees this project as an opportunity to help communicate the importance of being engaged in one's care to both Indigenous and non-Indigenous individuals receiving HD. As such, after the bedside nurses provide each patient with the survey and review the survey letter with the patient, the patient partner (when available) will be present in the unit and offer to discuss the study with people receiving hemodialysis in they feel this may be helpful in understanding the study and survey.

Surveys will be completed anonymously. Hardcopy surveys will be placed in blank envelopes by responders and collected by hemodialysis staff at each hemodialysis unit and picked up by the study coordinator on a weekly basis at each site. Participants may also mail completed surveys to Winnipeg site (stamped, addressed envelope will be provided in this situation).

**Survey B for healthcare providers** will be developed and piloted for face and content validity in collaboration with our Mind the Gap team members. The final survey will be sent by email with a hyperlink to complete the survey online directly into the secure online database.

All survey answers will be entered (either by participant if completed online or by research assistant if paper copy) into a secure, encrypted RED-CAP (Research Electronic Data Capture) database housed/managed at the University of Manitoba Centre for Healthcare Innovation. Access to the database will be granted to one research team member at each study site.

### *Data Analysis - Surveys*

Quantitative analyses will assess differences (via counts, frequencies and proportion) in the desire for specific mental health care issues or needs to be addressed across participant groups.

Demographic data collected from the survey will be analyzed and reported by frequency in aggregate to describe study participants and to ensure a diverse study sample of the Canadian in-centre HD population. In addition, subgroup analyses in terms of differences in priority by occupation, age, gender, ethnicity, and geographic region will also be performed.

Answers to free text questions will be collated using NVivo Version 12 and reviewed for common themes and codes. Data analysis will occur at the Winnipeg study site. Themes from the different participant groups (patients/caregivers and providers) will be compared and contrasted.

In the reporting, perspectives relating to mental health care challenges will be described. Potential strategies/innovations for improving mental health care in hemodialysis will be identified and categorized according to the thematic analysis. Data will be reported in two parts:

1. Description of mental health care needs and potential strategies/innovation priorities for each innovation area
2. Set of themes that elucidate the reasons why the groups have chosen priorities

Data collected from all Canadian sites will be analyzed and reported in aggregate and by geographic region.

***STATUS:*** *Data collection completed (Sept 2024). Data Analysis is nearing completion.*

## 2) PRIORITY SETTING PROCESS WORKSHOP (PSP):

Data gathered from the surveys will be used to develop and guide the PSP workshop. Multiple stakeholders will be identified and invited to participate in the PSP workshop.

Patients and caregivers with direct facility-based hemodialysis experience will be recruited from across Canada (Vancouver, Calgary, Edmonton, Winnipeg, Vancouver, Toronto, Ottawa, Montreal, Halifax). Each site will be asked to identify and suggest 5-6 in-centre people receiving hemodialysis and/or their caregivers that could participate in a two-day priority-setting workshop in Winnipeg. People receiving hemodialysis and their caregivers will be asked for verbal consent to contact by a nurse or other health care provider at their hemodialysis centre. If they consent to being contacted, the study research coordinator or research assistant will contact them in person (when possible)/ by phone or video conference (as per their preference) and provide them with the summary letter of information and invitation to participate. We expect to invite the following number of individuals:

i. Two to three people receiving hemodialysis/caregiver participants from each site, including approximately 7 Indigenous individuals (minimum total n=25).
ii. Nephrologists/site leads from sites participating in the survey (n=5)
iii. Researchers familiar with administering the survey in participating hemodialysis units (n=5).
iv. Nurses and other allied healthcare providers working in facility-based hemodialysis(n=6-10)
v. an Indigenous Elder and Knowledge Keeper (n=2)
vi. Policy-/decision-makers in hemodialysis from across Canada (n=6)

Participants in the workshop will generate the top challenges to mental health to address from a shortlist identified by the surveys. The research coordinator and research assistants will document the results and prioritizing as it occurs in real-time. With permission from the participants, notes, audio/video recording and photographs may be taken during the course of the PSP workshop.

Day 1 of the PSP workshop will generate the top priority challenges to mental health to address for individuals receiving hemodialysis utilizing a modified James Lind Alliance approach.[44]

Day 2 of the PSP workshop will employ a modified Co-Design process to identify the strategies to best address mental health care needs of people receiving hemodialysis.

These results will inform Phase 2 of the research project in which we will develop, implement and evaluate optimal evidence-based mental health support strategies for Canadians on hemodialysis.

Due to the nature of the topic of mental health care, a mental health counsellor or therapist will be available to debrief with participants after (or if necessary, during) each day of the PSP workshop.

**Survey and PSP Consent:**

Participants will be fully informed of the purpose of the research, that their participation is voluntary, that they may refuse to respond to any of the questions and that they may withdraw at any point in time. They will be asked to sign a consent form to participate in the focus groups or interviews, priority-setting process workshop this will be discussed with all participants prior to commencement. Participants will be offered the opportunity to ask their own questions and request additional information about the study by contacting the research team. Consent to participate in the survey will be implied by overt action (completion of the survey). Survey participants will not be asked to sign an informed consent form (waiver of consent).

***STATUS:*** *Completed. Workshop occurred June 7-9, 2024; manuscript in progress*.

**Aim 3: Design an evidence-based mental health support strategy tailored for Canadians receiving hemodialysis, and develop implementation and evaluation plans to test this strategy.**

**Dialectical Behavioural Therapy**

Based on data gathered through the Mind the Gap surveys and the Priority Setting Workshop, we have identified the top 5 challenges to mental well-being in facility-based hemodialysis as: loss of control, lack of acceptance and/or adjustment to the situation, lack of trust and confidence in the healthcare system and providers, dialysis-related symptoms, and feeling overwhelmed. After discussions with various stakeholders, we reached consensus that implementation of a Dialectical Behavioural Therapy (DBT) program, which targets 4 key concepts: mindfulness, distress tolerance, emotional regulation, and interpersonal effectiveness, has potential to address most of these five challenges. DBT has been used in many different settings (treatment of borderline personality disorder, substance abuse, improving self-esteem in adolescents, improving corporate culture) and populations, but to our knowledge has not been studied in the hemodialysis population.[45]

We will use a quasi-experimental pre/post study design to pilot two 12-week group DBT sessions in Manitoba that will be led by a licensed clinical psychologist who is trained and certified in delivery of DBT. Licensed clinical psychologist services will be provided by Tomfohr&Roos. Additional staff (e.g. Licensed Kidney Health Manitoba Social Worker at SOGH and/or a clinical psychology practicum student supervised by the licensed psychologist) may also co-facilitate the group depending on timing and human resources availability. An initial DBT group will meet in person at SOGH weekly for 12 weeks. Following completion of and incorporating feedback from the first session, a second virtual 12-week DBT group session will be implemented.

**Study Setting:**
Two 12-week DBT sessions (one virtual and one in-person) will be provided. The in-person sessions will be held weekly at the Seven Oaks General Hospital Campus in meeting rooms away from the hemodialysis unit. Virtual sessions will be video conferences held using the MS Teams platform.

**Study Population:**
*Inclusion Criteria:*
- Age ≥ 18 years old
- Individuals followed in the Manitoba Kidney Health Program at the SOGH or HSC sites with advanced chronic kidney disease not yet on facility-based hemodialysis but with plans to start within 1 month; OR
- Individuals followed in the Manitoba Kidney Health Program at the SOGH or HSC sites who have initiated facility-based hemodialysis within the last 90 days
- Able and willing to attend weekly DBT sessions (either virtually or in-person)
- Experiencing self-reported psychological distress related to advanced kidney disease or initiation of hemodialysis
- Deemed eligible to participate by study clinical psychologist

*Exclusion Criteria:*
- Unable to complete intervention due to planned relocation/transplant/modality change
- Unable to communicate in English
- Deemed by hemodialysis unit staff/physician/study psychologist to be unable to participate fully in study activities due to:
    - Actively participating in psychiatric care with psychiatric (DSM-5) diagnosis
    - Requiring referral for psychiatric care as per facility-based HD care provider assessment
    - Current psychotic symptoms
    - Cognitive impairment that would limit ability to participate in group or complete homework
    - Safety risk to staff (e.g. physical aggression)
    - Antisocial personality disorder or other issues that may limit ability to constructively participate in peer group
    - Severe comorbid substance use disorder (if present will offer referral to addictions resources or Addictions Psychiatry)

**Outcomes:**

***Primary Outcome <u>Feasibility measured by</u>*** *(collected at end of 12-week DBT session)*<u>:</u>

*a. Recruitment:* Number of individuals recruited/Number of eligible individuals approached ≥ 30%

*b. Attendance:*

i. Mean Proportion of total DBT sessions attended ≥ 50%

ii. Proportion of participants who attend all DBT sessions and complete all weekly homework sheets

*c. Study withdrawal:*

i. Proportion of individuals who miss ≥ 4 DBT sessions in a row
ii. Proportion of and reasons for study withdrawal

*d. Difference in recruitment and attendance rates between in-person and virtual DBT sessions*

***Secondary Outcomes:*** *measured by median change from pre-, to 6 weeks, and post-intervention (12 weeks):*
All participants will complete:
a. ***Anxiety symptoms*** measured by the LEVEL 2 – Anxiety – Adult (PROMIS Emotional Distress – Anxiety - Short Form). This 7-item self-reported survey asks about the current severity/presence of the individual's anxiety over the past 7 days, using a 5-point Likert scale ranging from 1 (never) to 5 (always).[46]
Time for completion: 5 minutes

b. ***Resilience*** measured using the two-item version of the Connor–Davidson Resilience Scale. This 2-item self-reported survey asks the individual to respond to the following statements: "I am able to adapt when changes occur" and "I tend to bounce back after illness, injury, or other hardships" using a 5-point Likert scale ranging from 0 (not true at all) to 4 (true nearly all of the time). Validated in multiple populations.[47]
Time for completion: Less than 5 minutes

c. ***Dialysis-related symptoms*** using the Edmonton Symptom Assessment System Revised (ESAS-r). This 10-item self-reported survey asks about the current severity/presence of common symptoms experienced by people receiving hemodialysis over the past 7 days, using an 11-point Likert scale ranging from 0 to 10 (i.e.; for pain: 0 = no pain at all; 10 = worst pain possible).[48]
Time for completion: 5 minutes

d. ***Emotional Distress*** using the self-reported National Comprehensive Cancer Network (NCCN) Distress Thermometer. This single-item measure asks the individual about their distress level experienced in the past 7 days, using a 10-point Likert scale ranging from 0 (no distress) to 10 (extreme distress). Additionally, there is a 39-item problem list used to identify potential sources of distress in individuals, categorized into five domains: physical, practical, social, emotional, and spiritual/religious.[49]
Time for completion: 1-10 minutes.

e. ***Well-being*** using the PROMIS Neuro-QOL V1.0 Positive Affect and Well-Being Short Form. This 9-item self-reported survey measures positive aspects of mental health and well-being in the past week, using a 5-point Likert scale ranging from 1 (never) to 5 (always).[50] Time for completion: 5 minutes

In addition, participants will complete a questionnaire seeking perspectives on participant experiences with the DBT program at the end of the 12 week DBT program.

f***. End of study participant questionnaire:*** The initial version of this 10-item self-reported questionnaire investigating perspectives on participant experiences in the DBT groups will be piloted by study patient partners to ensure readability and face validity and modified accordingly. The survey includes questions that require yes/no and open text answers to provide participants with ample opportunity to provide and explain feedback regarding the DBT program. We will use perspectives shared through this questionnaire to modify the plans for the virtual DBT session and future in-person DBT groups.

Time for completion: 5-10 minutes

***Total time for Completion of above surveys: 20-30 minutes/assessment***

To minimize survey fatigue, only individuals who endorse difficulty with the following items will be asked to complete the questionnaires listed below at each assessment time point.

g. ***Anger/Frustration*** measured using the LEVEL 2 – Anger – Adult (PROMIS Emotional Distress – Anger - Short Form). This 5-item self-reported survey measures the pure domain of anger over the past 7 days, using a 5-point Likert scale ranging from 1 (never) to 5 (always).[46]

Time for completion: 5 minutes

h. ***Pain*** using the PROMIS V1.1 - Pain Interference 6a Short Form. This 6-item self-reported survey measures the severity of pain and its impact on a person's ability to function over the past 7 days, using a 5-point Likert scale ranging from 5 (never) to 1 (always).[51]

Time for completion: 5 minutes

i. ***Sleep quality*** using the LEVEL 2 – Sleep Disturbance – Adult (PROMIS Sleep Disturbance – Short Form). This 7-item self-reported survey measures sleep quality, sleep depth, and restoration, including difficulties with falling asleep or staying asleep and satisfaction with sleep over the past 7 days, using a 5-point Likert scale ranging from 1 (not at all) to 5 (very much).[52]

Time for completion: 5 minutes

***Total time for additional survey completion:*** **15 minutes/assessment**

**Intervention:**

The specific curriculum/weekly session topics for the 12-week DBT program have been selected from previously developed DBT protocols used in the field by experienced and licensed mental health professionals and co-developed with study team patient partners (Table 1).

Before beginning either the in-person or the virtual program, participants will attend a brief orientation with the DBT clinical psychologist to review the program goals and ask any questions.

We plan to hold the in-person group DBT session first. Participant groups will meet weekly with the DBT therapist for a maximum of 2 hours, including snack or meal and social time. Meetings will be held within the SOGH campus but outside of clinical care areas and away from the hemodialysis unit (in the Chronic Disease Innovation Centre boardroom/SOGH meeting rooms/Wellness Institute meeting rooms depending on availability). Participants will receive reimbursement for transportation to and from sessions to facilitate attendance.

Subsequently we will review feedback from this first in-person group and potentially modify structure/plans for DBT sessions based on participant feedback and discussion with research team and then run the 12-week virtual DBT session. This group will meet weekly for a maximum of 90 minutes virtually through the secure Zoom Healthcare Platform with the clinical psychologist leading the group and one co-facilitator (individual who has a professional healthcare degree e.g. OT, social work, MD, nursing). Each week, participants will be sent an e-mail or text with an invitation link, as per their preference, for the group's Zoom meeting.

Both in-person and virtual DBT group participants will be provided with weekly session reminders and the relevant program materials by the research coordinator. This will include electronic or hardcopies of worksheets and handouts accompanying each week's content and videos that will be delivered by mail/email/drop off in HD unit as per individual preference. The group leader or co-leader may also check in with participants throughout the 12-week program periodically in an individual meeting.

**Table 1: Proposed Weekly Schedule for 12 Week DBT Program Delivery**

| | |
|---|---|
| **Weeks 1-3: Mindfulness (Foundation for All Skills)** | |
| **Week 1: Introduction to DBT & Core Mindfulness** | Overview of DBT and group expectations |
| | What is mindfulness? (Wise Mind, Reasonable Mind, Emotion Mind) |
| | Exercise: "Leaves on a Stream" meditation |
| | Homework: Mindfulness practice (observe and describe one activity mindfully) |
| **Week 2: Mindfulness – What & How Skills** | What Skills: Observe, Describe, Participate |
| | How Skills: Non-judgmentally, One-mindfully, Effectively |
| | Exercise: "Five Senses Grounding" |
| | Homework: Practice a "What" skill daily |
| **Week 3: Practicing Mindfulness in Daily Life** | Barriers to mindfulness |
| | Self-compassion and present-moment awareness |
| | Exercise: Body scan meditation |
| | Homework: Daily mindfulness journaling |
| **Weeks 4-6: Distress Tolerance (Coping with Crisis Without Making It Worse)** | |
| | Distraction skills (ACCEPTS: Activities, Contributing, Comparisons, etc.) |

| | |
|---|---|
| **Week 4: Crisis Survival Skills – ACCEPTS & TIPP** | TIPP (Temperature, Intense Exercise, Paced Breathing, Paired Muscle Relaxation) |
| | Exercise: Cold water face immersion (TIPP) |
| | Homework: Try two ACCEPTS skills during distress |
| **Week 5: Reality Acceptance – Radical Acceptance & Willingness** | What is radical acceptance? Letting go of suffering |
| | Turning the mind toward willingness |
| | Exercise: Half-smile & Willing Hands |
| | Homework: Notice resistance and practice radical acceptance |
| **Week 6: Self-Soothing & Improving the Moment** | Mindfulness of current thoughts |
| | Self-soothe with the five senses |
| | IMPROVE skills (Imagery, Meaning, Prayer, Relaxation, etc.) |
| | Exercise: Create a self-soothe kit |
| | Homework: Practice self-soothing at least twice this week |
| **Weeks 7-9: Emotion Regulation (Understanding & Managing Emotions)** | |
| **Week 7: Understanding Emotions & Checking the Facts** | Why we have emotions & how they work |
| | Checking the facts to reduce emotional intensity |
| | Exercise: Identify an emotion and fact check it |
| | Homework: Use "Check the Facts" worksheet on a distressing emotion |
| **Week 8: Opposite Action & Problem-Solving** | Opposite action: Changing emotions by acting opposite |
| | When to problem-solve vs. when to accept |
| | Exercise: Role-play opposite action for anger |
| | Homework: Use opposite action in a real-life situation |
| **Week 9: Building a Life Worth Living –**<br><br>**ABC PLEASE** | Mindfulness Review |
| | **A**ccumulate positive experiences |
| | **B**uild mastery & **C**ope ahead |
| | **P**LEASE (Physical health factors affecting emotions) |
| | Exercise: Create a "build a life worth living" action plan |
| | Homework: Identify & schedule one positive experience this week |
| **Weeks 10-12: Interpersonal Effectiveness (Building Stronger Relationships)** | |
| **Week 10: DEAR MAN – Asking for What You Need** | **D**escribe, **E**xpress, **A**ssert, **R**einforce, **M**indful, **A**ppear confident, **N**egotiate |
| | Exercise: Role-play using DEAR MAN |
| | Homework: Use DEAR MAN in a real-life situation |
| **Week 11: GIVE & FAST – Maintaining Relationships & Self-Respect** | GIVE (Be Gentle, Interested, Validate, Easy Manner) |
| | FAST (Be Fair, No Apologies, Stick to Values, Be Truthful) |
| | Exercise: Practice GIVE & FAST in a conversation |

| | |
|---|---|
| | Homework: Identify an opportunity to use GIVE or FAST |
| **Week 12: Bringing It All Together & Graduation** | Review of all DBT skills |
| | Identifying personal strengths and areas for growth |
| | Discuss plans for balance/ maintenance |
| | Exercise: Create a personal DBT plan for ongoing practice |
| | Homework: Reflect on how DBT has impacted your life |

**Recruitment and Consent for DBT Groups:**

At SOGH, there are currently 160 individuals that start hemodialysis per year. For the purposes of this study, we will aim to recruit 15 individuals, to account for no shows and dropouts, for the in-person DBT group from the SOGH Hemodialysis Units and Multi Care Kidney Clinic. For the virtual DBT group, we will recruit 20 individuals from SOGH and HSC Hemodialysis Units and relevant Kidney Clinics.

Prior to the initiation of the DBT pilot intervention, Dr. Bohm and the research coordinator will notify and orient healthcare staff to the study through an emailed letter of information and brief presentation to staff in the HD units and Kidney Clinics at both sites. An information poster advertising the DBT groups will be posted in the waiting room of Kidney Clinics and HD waiting rooms at both sites.

Potential recruits for the DBT groups will be screened for eligibility by a member of the individual's circle of care based on the inclusion criteria. If eligible, the individual's bedside or clinic nurse will approach them to briefly introduce the study and offer the potential recruit to opportunity be contacted by the study research coordinator for more information about the study by signing the Consent to Contact Form. This will then be returned to the study research coordinator. Participants will then be contacted by the study research coordinator (in person at hemodialysis/clinic or by phone call or email depending on the individual's preference) who will describe the study, the purpose of the research, the voluntary nature of participation and that participants may withdraw at any point in time and that the decision to participate or not will not impact their standard medical care. The coordinator will review the written consent form for the DBT intervention project with potential participants. Potential participants will be offered the opportunity to ask their own questions and request additional information about the study and will be given at least 24 hours to consider whether they want to participate or not. Consent to participate will be indicated through an individual's signature on the written consent form. All participants will read, sign, and date the consent form before undergoing any study procedures. A copy of the signed consent will be given to the participant. All original signed consents will be filed in a locked cabinet at CDIC.

**DBT Data Collection:**

Demographic and clinical data will be collected at time of consent directly from participant and medical chart review. Data collected will include CKD diagnosis date, dialysis status (planned HD start date, HD start date, HD shift and days), comorbidities, age, gender, ethnicity, employment status, highest level of education, approximate annual income, and marital status. Clinical data collected at baseline and Week 12 (study end) from hemodialysis chart will include dialysis clearance (Kt/V), medications, mean weekly

interdialytic fluid gains (in week before baseline assessment), and laboratory data. The blood work result for hemoglobin, albumin, potassium, calcium, phosphate, and parathyroid hormone taken at the closest time point to the study visit will be transcribed to CRF forms from the HD chart. Monthly blood work samples are taken every 4-6 weeks pre-dialysis on a mid-week dialysis day routinely as standard of care in in-centre hemodialysis. Hardcopy print out of results is placed in the hemodialysis chart as routine standard of care.

Study outcome assessments will occur at baseline, 6-weeks and following the 12-week DBT intervention (within +/- 10 days of this timepoint). Surveys will be distributed by the research coordinator and administered by hardcopy or electronically through participant's personal email (as per participant preference) and will be de-identified using each participant's unique study identifier. See Table 2.

**DBT Statistical Analysis:**

Descriptive quantitative analyses (counts, proportions) will assess feasibility outcomes. Baseline survey scores will be reported as median (interquartile range) and proportion of answers for each question on survey in each Likert scale category. Change in survey scores over time will be reported as median (interquartile range). Aggregate changes in scores of each survey between assessment timepoints will be compared using Mann-Whitney U test and Chi-square test as appropriate. Due to small sample size and exploratory nature of the study, statistically significant changes in secondary outcomes are not anticipated. However, P-value of $< 0.05$ will be considered statistically significant. All data analysis will be completed in SAS 9.5 (Carey,NC).

**Table 2: Study Schedule**

| SCHEDULED STUDY PROCEDURE | SCREEN AND ENROLLMENT (VISIT 0) | BASELINE (VISIT 1) | MID INTERVENTION 6 WEEKS (VISIT 2) | FINAL VISIT 12 WEEKS (VISIT 3) |
|---|---|---|---|---|
| HCP INCLUSION / EXCLUSION | X | | | |
| CONSENT TO CONTACT | X | | | |
| INFORMED CONSENT | X | | | |
| FINAL STUDY ELIGIBILITY | X | | | |
| DEMOGRAPHIC DATA | | X | | |
| MEDICAL HISTORY | | X | | |
| CONCOMITANT MEDICATIONS | | X | | X |
| LAB DATA | | X | | X |

| | | | | |
|---|---|---|---|---|
| **PRIMARY FEASIBILITY DATA** | | | | |
| **NUMBER APPROACHED** | | | | X |
| **NUMBER ELIGIBLE** | | | | X |
| **SESSION ATTENDANCE** | | | | X |
| **STUDY WITHDRAWAL** | | | | X |
| **SECONDARY OUTCOMES** | | | | |
| **LEVEL 2 –ANXIETY – ADULT (PROMIS EMOTIONAL DISTRESS – ANXIETY – SHORT FORM)** | | X | X | X |
| **CONNOR-DAVIDSON RESILIENCE SCALE (2-ITEM)** | | X | X | X |
| **EDMONTON SYMPTOM ASSESSMENT SYSTEM REVISED (ESAS-r)** | | X | X | X |
| **NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) DISTRESS THERMOMETER** | | X | X | X |
| **PROMIS NEURO-QOL V1.0 POSITIVE AFFECT AND WELL-BEING SHORT FORM** | | X | X | X |
| **LEVEL 2 – ANGER – ADULT (PROMIS EMOTIONAL DISTRESS – ANGER – SHORT FORM)** | | X | X | X |
| **PROMIS V1.1– PAIN INTERFERENCE 6a SHORT FORM** | | X | X | X |
| **LEVEL 2 – SLEEP DISTURBANCE – ADULT (PROMIS SLEEP DISTURBANCE – SHORT FORM)** | | X | X | X |
| **END OF STUDY PARTICIPANT QUESTIONNAIRE** | | | | X |

***Focus groups will now occur following the DBT pilot intervention if the intervention demonstrates feasibility, rather than after the above two activities as indicated in previous version of the protocol.***

**3) FOCUS GROUPS :** ***Collect additional perspectives regarding tailoring of DBT intervention and potential barriers/facilitators to implementation – WILL BE COMPLETED AFTER AIM 3 ONLY IF PILOT DBT INTERVENTION DEMONSTRATES FEASIBILITY***

Focus groups and interviews will help us gain deeper perspective and understanding as to how the DBT intervention should be tailored for people receiving HD with diverse characteristics and help identify potential barriers/facilitators to its implementation. Stakeholders will include healthcare providers, people receiving HD, caregivers, Indigenous consultants, researchers and policy-/decision-makers.

People with advanced kidney disease nearing hemodialysis, those receiving HD and caregivers with direct HD experience will be invited to participate in in-person focus group discussions. In total, we anticipate that 2-3 focus groups involving participants at two sites (Winnipeg and Halifax) will be conducted. We plan to conduct 2 patient/caregiver focus groups in Winnipeg with 6-10 participants per group (minimum total n=12), which is generally considered the optimum size of focus group discussions.[53] However, the number of focus groups will depend on when theoretical saturation is reached; the point when little or no new information informing the research objectives emerge. Due to logistical issues that may influence the number of participants that unexpectedly do not attend the focus groups, up to 12 participants will be scheduled for each focus group to ensure the minimum sample size is reached. In the event that a focus group participant is unable to attend a focus group (due to schedule conflicts, health issues or other reasons) we will invite them to a one-on-one interview in lieu of the focus group.

Participants will be recruited from dialysis units in Winnipeg, including the Seven Oaks Hemodialysis Unit and Health Sciences Centre (Central Dialysis Unit and Sherbrook Centre Hemodialysis Unit). A research team member will contact clinical staff (e.g. nephrologists, nurse managers and nurses from each of the facilities) to provide information about the study and seek to identify potentially eligible study patients. An information poster advertising the focus groups will be posted in the waiting room of Kidney Clinics and HD waiting rooms at both sites. Patients will initially be approached at their usually scheduled hemodialysis session by their bedside nurse who will briefly explain the study to them, provide an information letter, and determine their interest in participating. Patients who express interest will complete a consent to contact form and will then be contacted by a research assistant who will provide further details about the study and determine their willingness to participate in the focus groups. Eligible participants will be currently treated with HD, have initiated HD at least 2 months earlier, be aged 18 years or older, and be able to communicate in English.

To identify approaches and supports needed for culturally-appropriate care, we will seek to recruit 25% of participants in Manitoba from Indigenous (both First Nations and Metis) backgrounds to participate in focus groups and interviews. Following OCAP principles[54] we will seek the wisdom of Indigenous stakeholders, including patients, healthcare workers and Indigenous knowledge keepers.[55] At least one of the Winnipeg

focus groups will focus on the Indigenous perspective and will include Indigenous facilitators and an Indigenous Knowledge Keeper***. Details of this focus group will be included in a subsequent amendment that will be submitted to ethics after additional consultation with Indigenous communities/organizations in Manitoba to assist with design, content and facilitation.***

When potential participants are contacted, they will be asked whether they have a caregiver who might also be interested in participating. Caregivers may be a family member or significant person in their life who is intimately aware of their illness. Attempts will be made to recruit people receiving dialysis of different genders and ethnicity, from a range of ages, who are originally from both urban and rural settings. Advertisements informing participants and their caregivers of the research opportunity will be posted in the dialysis unit waiting areas, on the CNTN, Can-SOLVE and Kidney Foundation of Canada websites blasts.

People receiving HD and caregivers who are eligible and willing to participate will sign an informed consent form. Focus group participants will be offered $50 reimbursement to cover their time and transportation costs. Due to the nature of the topic of mental health care, a social worker, mental health counsellor or therapist will be available to debrief with participants after (or if necessary during) each focus group.

Should recruitment for focus groups be difficult due to participants' dialysis or work schedules, inability to travel, and other commitments, individual interviews will be considered as an alternative. The same recruitment procedure, consent, data collection and debriefing procedures would apply in these situations.

The focus groups will be 90-120 minutes in duration and conducted in a location relatively accessible to patients and caregivers. A facilitator will moderate the focus groups, while a co-facilitator will observe and record the contextual details of each discussion. We will use MS teams and its built in transcriber software to record and transcribe focus groups. A question guide with open-ended questions will be developed to explore the topics of interest. An interactive activity will be used to generate ideas as well as a voting exercise to discuss priorities, choices, and reasons for these choices. Poster boards/White boards and sticky notes will be used to facilitate the discussion. The welcome/introductions will be approximately 5-10 minutes while the subsequent focus group discussion will be 60-80 minutes in duration. See focus group discussion guide for more detail. Participants will also complete pre-focus demographic questionnaires. The focus group guide will be pilot tested and refined with project patient partners to ensure clarity of the questions.

In the circumstance where an interested individual cannot attend a focus group, individual semi-structured interviews will occur in lieu of the focus group. Interviews will be 30 to 45 minutes in duration and ideally conducted face-to-face at a location convenient for the participant, but via telephone or video-call if necessary. See interview guide for details. One interviewer will conduct the interviews. All interviews will be audio-recorded and transcribed verbatim using MS Teams platform.

All participants will be asked for their consent to audio record the focus groups discussions and the interviews. Participants will be assured that their identity will be kept confidential by researchers. A consent form approved by the University of Manitoba

Health Research Ethics Board will be completed prior to the commencement of their focus group session or interview.

The same study protocol, including DBT implementation study and focus groups with patients/caregivers will be implemented in Halifax, following ethics approval from Dalhousie University. Ideas and de-identified direct quotes from focus groups and interviews will be used in a combined form for final reports and presentations of the evaluation information. At no time will names of participants be associated with any of the data collected or presented.

**Data Analysis - Focus Groups/Interviews**

Analysis of focus groups and interview data will be led by two investigators who will:

1) Achieve immersion by reading the initial focus group/interview data in its entirety to acquire an overall sense of the data;
2) Read the focus group or interview data and highlight words or phrases that capture key concepts, which become the codes;
3) Take notes of initial impressions, thoughts, and interpretation;
4) Develop codes;
5) Sort codes that are related to each other into themes and subthemes.

Investigators will meet together to verify themes and their descriptors for each group of participants. Codes will be generated from the initial focus group and interview data independently and they will be systematically applied to identify themes and patterns for subsequent groups. The process will be reflexive and interactive as continual data collection and data analysis will shape each other.[56] For example, code titles or definitions identified based on the first focus groups may be modified based on data collected during the second, and new codes may be added requiring recoding of the first focus group transcript. An Indigenous research assistant will participate in the analysis of the Indigenous focus group.

Mental health care gaps and potential innovations and solutions will be categorized accordingly. Themes and subthemes will be identified under these overarching categories, including the reasons why strategies have been chosen. Definitions will be developed for existing codes, themes, and subthemes, and exemplars of these will be reported in the findings. Investigators will meet together to verify themes and their descriptors for each group of participants. Themes will be presented to the remaining investigative team, including patient partners for verification.

Data collected from both study sites will be analyzed and reported in aggregate. Quantitative demographic data from the participant questionnaires will be analyzed and reported by frequency to describe our participants. We will review results of any analysis which is concerned with Indigenous community membership with the Can-SOLVE CKD Indigenous Peoples' Engagement and Research Council (IPERC), an Indigenous Elder Knowledge Keeper and Indigenous Patient Partners and Indigenous Research Assistants to help with interpretation of our findings.

**Risks and Benefits of Study Participation:**

Participants in this study will discuss and be asked about their mental health. Previous work has demonstrated that asking adult research participants about their past experiences in these domains is no more distressing than asking about other personal experiences (e.g. scholastic achievement; body image) and is not typically harmful.

It is possible that some participants will find participating in the survey, PSP, DBT pilots and focus groups therapeutic and/or rewarding. Participants may benefit from improving mental health and building connections with other patients going through similar experiences. Some people may find it meaningful to be part of a research project. The information we learn from the project will benefit society's understanding of the challenges to mental health in people receiving hemodialysis and their solutions.

However, no benefits related to study participation can be guaranteed. DBT participants will be reimbursed for their transportation to in-person DBT group sessions and will share a meal or snack with other group participants. Focus group participants will receive a $50 honorarium for their time and expenses related to attendance. Additional reimbursement for childcare as needed will be provided as well.

Conversely, it is possible that some participants may experience psychological discomfort while participating in DBT or focus group sessions and/or while answering questions related to study activities. To minimize the possible distress due to answering questions about mental illness, participants will be told during the consent process that they may skip any questions that make them feel uncomfortable and that they are free to discontinue participation at any time without penalty.

Due to the nature of the topic of mental health care, external to research, the kidney care staff (social workers and nephrologists) will manage the well-being of clients through standard clinical care processes. Additionally, we will provide participants with a list of resources available outside of therapy sessions, including the environmental scan of mental health resources available for people receiving hemodialysis in Manitoba, SOGH renal social workers, the elder partnering with the Mind the Gap project and the mental health crisis line to debrief with participants as necessary. Participants who wish to withdraw will also receive a list of mental health resources in Manitoba. At the end of the DBT program, all participants will also receive this list again.

**Ethical considerations**

Ethical approval for the overall research project will be obtained from the University of Manitoba and will be sought at each individual study site, including the University of Calgary, Health Research Ethics Board for the Calgary site. There are no specific risks associated with participation in this research project. While there will be time commitments associated with attending the focus groups, patient and caregiver participants will be provided with $50 for their time and expenses. The time required for participating in the priority-setting process workshop will be two full days, including one overnight, of which participants will incur no costs; all travel, accommodation, food and per diems will be provided. In addition, participants will contribute their voices and opinions to the improvement of clinical service provision.

**Data management**

We will maintain appropriate research records for this study, in compliance with ICH-GCP, and institutional requirements. For this study, CRFs will be the primary record of the patients' participation in the study but will be supplemented by hard copy/electronic documentation of outcome assessments (e.g. completed surveys and questionnaires).

Data will be submitted for every survey respondent and DBT pilot or focus group participant who is enrolled in the study, regardless of duration via transcription of paper Case Report Forms or direct entry into RedCAP, a secure electronic data capture system housed at the University of Manitoba. Data available from the source documents will be de-identified using a dedicated participant ID number. No identifiable information will be entered.

Paper CRFs will be completed in black or blue ink only and be legible. If an entry on a CRF requires change, the correction will be made by drawing a single line through the incorrect entry, followed by entering the correct data and initialing and dating the entry. Correction fluids, markers, erasures or any form of obliteration on the CRFs will not be permitted. All fields will be completed. If data are not available, a straight line will be drawn through the applicable fields and the words "None" or "N/A" will be written. The study research assistant will be responsible for entering the data into the secure, password-protected computerized REDCap database.

**Anonymity, Confidentiality and Data Security**

All members of the research team will respect study participants' privacy and confidentiality throughout the study. Measures will be taken to ensure that all the data collected for this study will remain confidential in accordance with privacy legislation. Study personnel will not transmit documents, other than that previously specified, or samples containing personal health identifiers (PHI) at any time over the course of the study. Each participant will be assigned a unique code and these numbers rather than names will be used to collect, store, and report participant information. Full names and other identifying information will not be revealed unless required by law and/or for the applicable REB review, or for auditing purposes. The Subject Identification Code List (i.e. participant key) that links the identity of the participant with subject ID for de-identified data will be maintained with the trial master file. The master file will be maintained both in electronic and hard copy format. The electronic file will be encrypted and stored on a dedicated research server that only the PI and study research staff will have access to. The identity of the participants will not be revealed in any published data or in presentation of the information obtained as a result of this study. Findings will be reported in aggregate.

Anonymity and confidentiality will be maintained as much as possible for PSP, DBT pilot intervention and focus group participants but cannot be guaranteed due to the nature of group participation. Ground rules will be established and reviewed at the beginning and end of the PSP workshop, each DBT session and focus group emphasizing the confidentiality of information shared within the group. Taking these precautions will assist in maintaining confidentiality of the data collected. Audio recordings and questionnaires will be stored in a locked filing cabinet in a locked office at the University of Manitoba for a period of 10 years after study completion and will then be destroyed. Electronic data including the study participant key and transcripts of audio files will be

kept in REDCAp or a password-protected file on a research server at University of Manitoba accessible only to Dr. C. Bohm and research staff involved in the study for 10 years. Anonymous quotes from the focus groups, interviews, surveys, DBT groups, and PSP may be presented in the publications of aggregate results for illustrative purposes.

Study records will be retained for 10 years after study completion. When the archiving requirements have expired, any written records associated with this study will be destroyed using confidential shredding and the electronic database used for analysis will be deleted.

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## Appendix A. Project Framework Updated 2025

| Column A: Grant Year | Column B: Objectives | Column C: High-Level Key Activities |
|---|---|---|
| **Years 1-2** | **Key Objective 1: Develop an accessible inventory of all mental health supports available to Canadians on hemodialysis.**<br><br>*Knowledge to Action Framework Stage:*<br><br>*- Identify problem, review, select knowledge* | |
| | Sub-Objective 1.1<br><br>Perform an environmental scan of mental health resources for people receiving dialysis treatment across Canada | A. Identify resources in each province - Complete<br>● One province at a time, conduct Google/web search for resources, including health agencies and public facing<br>● Maintain an audit trail of environmental scan<br>● Identify target audience (i.e. patients and clinicians) and tailor accordingly<br>● Identify kidney specific / generic mental health and organize accordingly<br>● Identify French-speaking collaborators to help with Quebec resources<br>● Consult kidney experts, including multidisciplinary practitioners, KFOC, and patient partners to solicit feedba<br>(*Led by Schick-Makaroff*) |

| | | |
|---|---|---|
| | | B. Identify and connect with consultants in each province to confirm resources - Complete<br>● Consult experts, including patient partners, on the environmental scan for each province<br>● Identify gaps in resources to be addressed in subsequent phases of project<br>(*Led by Schick-Makaroff/Bohm/Provincial Leads*) |
| | | C. Identify resources for mental health care specifically Indigenous people in Manitoba - Complete<br>● Consult with Indigenous organizations in Manitoba (FNHSSM and Ongomiizwin)<br>● Consult with Indigenous patient partners and healthcare providers<br>● Consult with Indigenous Knowledge Keepers (project Knowledge Keeper)<br>(*Led by Bohm*) |
| | | D. Consult and partner with other mental health associations in Canada to ensure resources are identified in environm<br>● Canadian Mental Health Association<br>● Mental Health SPOR Network<br>(*Led by Schick-Makaroff/Bohm*) |
| | | E. Develop content to make environmental scans accessible online - Complete<br>● As each province's environmental scan is completed, work with Can-SOLVE web designer (Graham Pollock health agencies to finalize and house the final resource<br>(*Led by Schick-Makaroff*) |

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| **Years 1-2** | **Key Objective 2: Identify culturally sensitive, individualized approaches to mental health care for people on hemodialysis**<br><br>*Knowledge to Action Framework Stage:*<br><br>*-Adapt knowledge to local context/Assess barriers/Select and Tailor Interventions* | |
| | Sub-Objective 2.1<br><br>Identify key targets, components,<br><br>priorities, and preferences for<br><br>individualized mental health support<br><br>strategies for Canadians on hemodialysis | Survey / Prioritizing Exercise using James Lind Alliance approach Complete<br><br>● Which aspects of mental health in hemodialysis are most important to address?<br>● What treatments are most acceptable and have potential to help? Complete<br>● Where/how/by who should mental health care be provided? (e.g. in HD unit, online, group, individual, famili<br>● Discuss with different stakeholders how to adapt these aspects into intervention Ongoing<br>● Discuss specific aspects of mental care with Indigenous representatives' (see Obj 2.2 below)<br><br>(*Led by Bohm*) Ongoing |

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| | Sub-Objective 2.2:<br>Identify challenges to mental health care for Indigenous people on hemodialysis | Qualitative study identifying challenges to care in Indigenous individuals receiving hemodialysis in Manitoba – Engag<br>groups ongoing<br>● Engage Indigenous community in Manitoba (FNHSSM/Ongomiizwin) for feedback, comments and consensu<br>● Present findings to community and clinicians with recommendations for support Pending |
| | Sub-Objective 2.3<br>Identify the effect of gender on key challenges and lived experiences in individuals with depression receiving hemodialysis | A. Nursing knowledge in hemodialysis and depression care –<br>● Integrative review, guided by Whittemore and Knafl<br>B. Synthesis on sex and gender differences in people receiving dialysis and experiencing depression<br>● Scoping review, guided by Arksey and O'Malley, updated by Levac<br>C. Qualitative study, guided by Interpretive Description, exploring adult women's experiences of depression while re<br>● Present findings to clinicians, along with recommendations for support<br>(*Led by PhD trainee, Primrose Mharapara; Schick-Makaroff*) |

<table>
<tr><td>Years 3-4</td><td colspan="2">Key Objective 3: Informed by Objectives 1 and 2, develop, implement and evaluate optimal evidence-based mental health support strategies for Canadia<br><br>Knowledge to Action Framework Stages:<br>-Adapt knowledge to local context/Assess barriers/<u>Select and Tailor Interventions</u><br>- Implement Interventions, Monitor Knowledge Use, Evaluate Outcomes<br><br>Implementation Framework: Consolidated Framework for Implementation Research (CFIR)<br>Evaluation Framework: Reach, Effectiveness, Adoption, Implementation, Maintenance Framework (RE-AIM)</td></tr>
<tr><td></td><td>Sub-objective 3.1<br><br>Develop an intervention to support mental health care for individuals receiving hemodialysis in Manitoba (and Nova Scotia – currently)</td><td>Using an iterative approach and engaging community stakeholders/patient partners/clinicians - Ongoing<ul><li>Incorporate information obtained from Objectives 1 and 2</li><li>Develop intervention addressing a priority mental health issue Identified in Obj 2.1 and 2.2<ul><li>Submit ethics for Dialectical Behavioural Therapy (DBT) Pilot Intervention</li><li>Recruitment</li></ul></li><li>Develop implementation strategy for this intervention<ul><li>Implement & evaluate DBT Pilot Intervention</li><li>Focus Groups to tailor DBT Pilot Intervention</li><li>Analysis and further tailoring of DBT Pilot Intervention</li><li>Additional tailoring of DBT Pilot Intervention for Indigenous people on HD</li><li>Knowledge Translation</li></ul></li><li>Develop evaluation plan for this implementation strategy</li></ul>(Led by Bohm)</td></tr>
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| | Sub-Objective 3.2<br>Implement and evaluate pathway for mental health care for Albertans receiving dialysis | Using a person-centred evaluative framework - Ongoing<br>● Develop knowledge translation strategies to support implementation of the pathway<br>● Evaluate pathway using person-centred outcomes (patient-reported outcome measures) and person-centred qu<br>(*Led by Schick-Makaroff*) |
| | Sub-Objective 3.3<br>Provide recommendations on how to tailor a Mental Health Pathway for other Canadian provinces | Tailor Alberta's pathway for mental health (e.g. assessment tools; dedicated staff member) A) MB context, and B) NS yet<br>*(Led by Bohm/Tennankore/Schick-Makaroff)* |