RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

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

Dialectical Behavioural Therapy (DBT) Groups

Principal Investigator: Dr. Clara Bohm
Chronic Disease Innovation Centre, Seven Oaks General Hospital
2LB19-2300 McPhillips St, Winnipeg, MB R2V 3M3

Research Coordinator: Jordan Bankowski | (204) 631-3834 | jbankowski@sogh.mb.ca

Sponsor: Canadian Institutes of Health Research (CIHR)

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

BACKGROUND

Mental health "**Mental health**" refers to the state of one's psychological and emotional well-being. It's about one's feelings and thoughts, whether they are experiencing positive emotions, such as happiness and contentment, or facing challenges like stress, sadness, or anxiety. This is not the same as mental illness, but poor mental health can lead to physical and mental illness.

People with chronic kidney disease face a significant burden on their mental health and although recognized as a serious issue, an approach to addressing mental health care for people with kidney disease and kidney failure is lacking. New models are needed to meet the mental health needs of people with kidney disease in Canada.

In earlier stages of the Mind the Gap project, we identified that the top 5 challenges to mental health in people receiving hemodialysis were:

1. *Loss of control*
2. *Lack of acceptance and/or adjustment to the situation*
3. *Lack of trust and/or confidence in the healthcare system and providers*
4. *Dialysis-related symptoms*
5. *Feeling overwhelmed*

Possible solutions identified to the above mental health challenges included counselling/therapy and peer support. **Dialectical Behavioural Therapy (DBT)** is a form of counselling that focuses on learning ways to change unhelpful thoughts and behaviours and teaches skills for interpersonal relationships. Group DBT could help address most of the priority challenges to mental health listed above and provides an opportunity for peer support.

PURPOSE OF STUDY

This research study is being done to find out if people who have advanced kidney disease or are receiving hemodialysis:

1. Are interested in participating in a 12-week group Dialectical Behavioural Therapy program.
2. Can attend and participate in a 12-week group Dialectical Behavioural Therapy program.
3. Have improved mental health after participating in a 12-week group Dialectical Behavioural Therapy program.

STUDY PROCEDURES

You will be asked to participate in a DBT group that includes people who have advanced kidney disease or are receiving hemodialysis and the researchers. One DBT program will occur in-person and a separate DBT program will occur virtually. You will be assigned to attend only one of these programs depending on your preferred program format. Before beginning either the in-person or the virtual program, you will attend a brief orientation with the DBT therapist to review the program goals and ask any questions you may have about the program. Groups will meet weekly, and sessions will run once a week for 12 weeks.

A. <u>In-Person DBT Group</u>

Groups will meet for a maximum of 2 hours, including snack or meal and social time, with 10-15 other participants, the DBT therapist who is leading the group and one co-facilitator (individual who has a professional healthcare degree e.g. occupational therapist, social work, MD, nursing). Sessions will be held within the SOGH campus but outside of clinical areas and away from the hemodialysis unit (in the Chronic Disease Innovation Centre boardroom, SOGH meeting rooms or Wellness Institute meeting rooms depending on availability).

B. <u>Virtual DBT Group</u>

You will need access to an e-mail, device, and internet access for the virtual DBT group. Groups will meet for a maximum of 1.5 hours virtually through the secure MS Teams virtual planform with 15-20 other participants, the DBT therapist leading the group and one co-facilitator (individual who has a professional healthcare degree e.g. occupational therapist, social work, MD, nursing). Each week you will be sent an e-mail or text with an invitation link, as per your preference, for the group's virtual meeting that week.

Both in-person and virtual DBT group participants will complete 8 short questionnaires regarding their mental health before the program starts at 6 weeks into the program, and after the DBT program ends (12 weeks). These questionnaires ask questions about your wellbeing, distress tolerance, anxiety, ability to cope, resilience, sleep, pain, anger and will take approximately 20-30 minutes to complete at each study assessment time point. Participants will also complete an end of study questionnaire (10-15 minutes to complete) to gather their perspectives on their experience in the DBT program. 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 your preference. The group leader or co-leader may also check in with all participants throughout the 12-week program periodically in an individual meeting.

The total time commitment (in sessions and home assignments) for this DBT program study will be approximately 36-39 hours:
Questionnaires will take approximately 1.5-2 hours in total over the 3 study assessment time points (pre-, 6-week, 12-week, post-intervention).
The DBT program content will be 25 hours of commitment (around 2 hours/week + orientation).
Home assignments and program material will take the additional 9-12 hours over the 12-week program.

RISKS AND DISCOMFORTS

Participants in this study will 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 may experience psychological discomfort while participating in therapy sessions and/or while answering the questionnaires. To minimize possible distress due to answering questions about mental illness, you may skip any questions that make you feel uncomfortable and you are free to discontinue your participation at any time without penalty.

Due to the nature of the topic of mental health care, external to research, the hospital staff 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 an environmental scan of mental health resources available for people receiving hemodialysis, Seven Oaks General Hospital renal social workers and the mental health crisis line to debrief with participants before, after, or if necessary, during.
Dr. Clara Bohm or Jordan Bankowksi (204) 631-3834 can be called if you want or need any help or support.

BENEFITS

You 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 and their solutions in people receiving hemodialysis.

PAYMENT FOR PARTICIPATION/COSTS

There is no cost to you for participating in this study.
The program and all program materials with be provided to participants free of charge. Participants in the in-person DBT group will receive reimbursement for transportation to and from sessions and a meal or snack will also be provided free of charge immediately prior to the sessions. Reimbursement for childcare as needed will be provided for participants in both the in person and virtual sessions.

CONFIDENTIALITY

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Your name will not be used in any documents based on the research. Only the researchers(s) will be able to get information from the study. Privacy will be kept as much as possible within each group. Information collected will be kept confidential. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Code names or numbers will be used on field notes. Any hardcopy notes, consent forms, transcripts of focus groups sessions and audiotapes from the study will be kept and locked at the offices at the University of Manitoba. In addition, any electronic files including those containing identifying information (study key) will be password protected and kept on secure research server at the University of Manitoba accessible only to the principal investigator and her research staff. The University of Manitoba Research Ethics Board may review research-related records for quality assurance purposes. At no time will your name be associated with any of the data collected or presented.

In this study, your medical records (e.g. medical chart) will be accessed so that our team can collect information for the study, with your consent. Only the Manitoba research team will have access to your chart, and with the purpose of obtaining and verifying the information about you at the time of consent directly from you and your medical chart, will collect the following information: Chronic Kidney Disease diagnosis date, dialysis status (planned hemodialysis start date, hemodialysis start date, hemodialysis shifts and days), medical problems, stage of kidney disease, age, gender, ethnicity, employment status, highest level of education, approximate annual household income and marital status. Clinical data collected at the beginning and end of the study will include dialysis clearance (Kt/V), medications, weekly fluid gains, and laboratory data. There is no additional blood work required as part of this study. We will use the results from bloodwork being taken for usual clinical care for this study. Results of all study questionnaires will be de-identified using each participant's unique study identifier. Every effort will be made to ensure information collected for the study from participants and charts will not have any identifiers and will only be marked with the unique study identifier.

You have the right to access, review, and request changes to your personal health information. All participants will be contacted in person or via e-messaging (email or text, per your preference). The contact information that you provide will solely be used to provide reminders for DBT sessions, if the DBT therapist needs to contact you for clinical care and for providing a virtual link for the DBT virtual group. All participants will be contacted individually to protect everyone's privacy. The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY

Your participation is voluntary. You may refuse to answer any of the questions. You may withdraw at any time. You also have the right to ask questions and ask for more information whenever you like. If you do not participate it will not jeopardize your health care or your ability to access health care services.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

There are no other requirements of you or expectations other than what is outlined above. You may be contacted about participating in future phases of the study if you indicated that you would be interested in this below. Any participation in future studies would require new consent.

QUESTIONS

You are free to ask any questions that you may have or for further information. If any questions come up during or after the study or if you have a research-related injury, contact the study doctor and the study staff:

Name: Jordan Bankowksi / Dr. Clara Bohm
Phone: (204) 631-3834
Email: jbankowski@sogh.mb.ca

For questions about your rights as a research participant, you may contact:
The University of Manitoba, Bannatyne Campus Research Ethics Board
Email: bannreb@umanitoba.ca
Phone: (204) 789-3389

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have read this consent form. I have had the opportunity to discuss this research study with *Dr. Clara Bohm* and/or her study staff. I have had my questions answered in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to be contacted for future follow-up in relation to this study: Yes ___ No ____

☐ I consent to participating in the in-person Dialectical Behavioural Therapy sessions

☐ I consent to participating in the virtual Dialectical Behavioural Therapy sessions

_____	_____	_____
Participant's Name	Participant's Signature	Date

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

_____	_____	_____
Research Staff's Name	Research Staff's Signature	Date

The University of Manitoba Health Research Ethics Board has approved this research study. A signed copy of this consent form has been given to you to keep for your records and reference.