UNIVERSITY OF ALBERTA

Information & Consent Form

MAP-AP: Mental Health Assessment and Prescribing by Alberta Pharmacists

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Background:

Mood and anxiety disorders are the most common mental illnesses among Canadians that can significantly impact your quality of life. It is important to manage, however, the stigma of mental health prevents patients from getting the support and resources that can help maximize the chances of successful treatment and long term control.

Pharmacists work with patients and their physicians to provide mental health care. Their involvement with medications may help patients with depression or anxiety. Overall, this might lead to better control of mental health illness.

Purpose:

You are being asked to take part in a research study to find out if a community pharmacy mental health management program can help reduce your depression and anxiety symptoms.

Procedures:

If you are ≥18 years of age, with a diagnosis of depression and/or anxiety and currently started on medications for this diagnosis--you will be asked to take part in the study, which will take place over 6 months.

If you agree to take part in the study, you will be randomly assigned to take part in one of 2 study groups **(Control or Intervention)** and be sent a questionnaire that will ask about your mood, feelings, emotions, and activities. These questionnaires will take no longer than 10 minutes to complete. This questionnaire will be sent to you directly through a secure electronic link (i.e. email, text messaging) for you to complete on your own. The questionnaire results will be available to study investigators and your pharmacist, but will only be linked to your participant identification number.

You will have to repeat this questionnaire up to 3 additional times during the 6 months you are in the study.

You may be asked to meet with your pharmacist online up to 3 times over 6 months, depending on the group you are assigned to. These online meetings will usually last 20-30 minutes, using telehealth services which are HIPAA, GDPR, PHIPA/PIPEDA, & HITECH compliant (to replace in-person interviews & limit COVID-19 related risks). More frequent

online meetings may be requested if your pharmacist thinks it is clinically important and/or you may receive a courtesy phone call after changes to your medications.

If assigned to the **Intervention Group**, in addition to standard physician and pharmacist care, the pharmacist will review and discuss with you about your medications, diet, physical activity, sleep, mental health, behaviour and other relevant topics in order to measure your depression and/or anxiety.

To help you achieve your goals, the pharmacist will work with you and your physician to improve the management of your depression and/or anxiety. This may involve the pharmacist prescribing medications or adjusting medication doses, ordering lab work, or making the referral with your physician to see a psychologist and/or psychiatrist.

Your physician will receive a letter from the pharmacist to let him/her know you agreed to participate in this study. The letter will also contain detailed information of what the study is about.

If assigned to the **Control Group**, you will continue to receive standard care from your pharmacist and physician. In both groups, you will also receive a brochure from Alberta Health services Access mental health with contact information for additional mental health resources available in Calgary.

Possible Benefits:

The pharmacist delivered program may help you reduce your depression and/or anxiety symptoms by:

- Using assessment skills and training in Major Depression Disorder and Generalized Anxiety Disorder to identify needs to adjust your medication dose, stop, and/or prescribe additional medications, if needed.
- Being available to follow-up on these medication changes in person and/or over the phone.
- Working closer with your physician to improve your medication treatment and management of your depression and/or anxiety
- Discuss with you and your physician to make the referral to a psychiatrist and/or psychologist, if needed
- Provide you additional information and resources to help you understand your medications.

Our hope is that this study shows how pharmacists can be used to improve your depression and/or anxiety care.

Possible Risks:
Overall, the main risks that may occur from your participation in this study may include:

- Side effects that occur with medication dose changes and may vary depending on the medication used, the most common being:
    - Nausea
    - Increased appetite and weight gain
    - Altered sex drive
    - Fatigue and drowsiness
    - Trouble sleeping
    - Dry mouth
    - Blurred vision
    - Constipation

- Time spent for additional in-person or telephone pharmacy visits and/or follow-ups
- Having to go for additional blood tests (only if required)
- Medication costs if changes to your medication therapy are prescribed

While we hope your depression and/or anxiety is managed effectively, they may not be reduced by the end of the study. Being assigned to the Control group, you will be receiving the same

Confidentiality:

Your questionnaire results and types of pharmacist interventions will be the only information, from you and your pharmacist, that the research team will be collecting. This will be submitted electronically through a secured link to the research team. This information will only be attached to your study participant number and no information that could identify you will be collected.

This information will not be released unless we are required to do so by law or revealed outside the research office (which is in a secure area). No information that could identify you will be included in any report published from the study. The University of Alberta requires us to keep data from the study for five years. If you withdraw from the study, your data will not be destroyed. The Health Research Ethics Board has authorized us to use the data for this study only. Any future use of the data requires additional ethics approval.

By signing the consent form you give permission to study staff to access your questionnaire and pharmacist intervention results.

Voluntary Participation, Post-Participation, and/or Decision to Withdrawal:

You do not have to take part in the study at all and you can quit at any time during the study. If your pharmacist identifies a risk which may affect your choice to continue in the study, we will let you know as soon as possible and discuss your options to continue or withdraw.

If you choose to not take part in this study at any time and/or you complete your participation in the study, the quality of your care will not be affected, and you can continue to receive the same level of care or receive similar care as the intervention group, from your pharmacist.

Reimbursement of Expenses:

You will not be paid for participating in this study.

Contact Names and Telephone Numbers

If you have any concerns about any aspect of this study, please contact the University of Alberta Health Research Ethics Board at (780) 492-2615. This office is not connected with the researchers setting up this study.

You may also contact Dr.Yazid Al Hamarneh (Primary Investigator) (780) 492-9608 or Dr.Matt Chow (Primary Investigator (587) 999-0778

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CONSENT FORM

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	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached Information Sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss this study?		
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?		
Has the issue of confidentiality been explained to you?		
Do you agree to allow the investigators to contact you about future studies?		
Do you understand who will have access to your study records?		
Do you understand that your family physician WILL be notified about your participation in the study?		

Who explained this study to you?

_____

I agree to take part in this study: YES □ NO □

Signature

_____

(Printed Name) _____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Person Obtaining Consent _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT