OPTIMUM

Optimizing Depression Treatment in Older Adults

INFORMATION FOR CLINICIAN PARTNERS

camh
Centre for Addiction and Mental Health

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

To Refer a Patient:
Call local OPTIMUM Recruitment Line
1-866-539-3510

REB REF #086/2016

Patient-Centered Outcomes Research: "Research Done Differently"

This project is funded by the Patient-Centered Outcomes Research Institute

- A Non-profit organization
- Created by the ACA: funded by US treasury, Medicare and Medicaid, and a fee on commercial insurance.

What is different about this type of research?

- **Comparative effectiveness trials**: Which treatment works best, for which patient, in real world care settings?
- **Stakeholder engagement:** Patients, physicians, and families are intentionally involved in every stage of the research process.

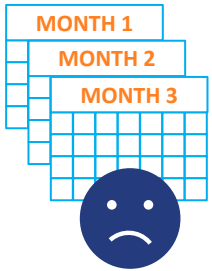
What is Treatment Resistant Depression?

Major depression that persists despite treatment with two or more standard antidepressants.

For example:

Patient took **sertraline** faithfully for three months but did not respond (or not fully);

Then patient took **venlafaxine** faithfully for three months – with the same outcome.



Trials must be adequate in dose, duration (12 weeks), and adherence.

It’s important to treat depression!

Persistent depression in older adults **accelerates aging and cognitive decline**.

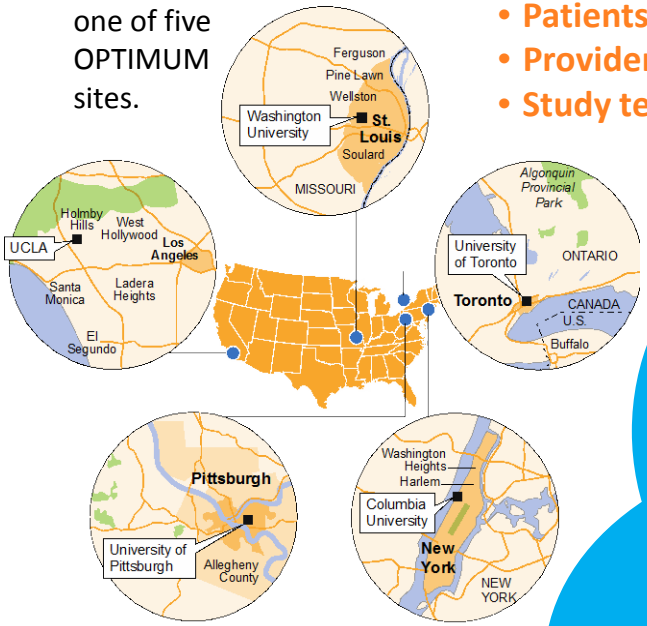
- Many older adults do not respond to first-line antidepressant treatment.
- The challenge: deciding which medication strategy will be most effective and safe for your older adult with depression.

You are helping us find the most effective treatments.

You are an important part of the team

The OPTIMUM study team partners with you to treat older adults with depression.

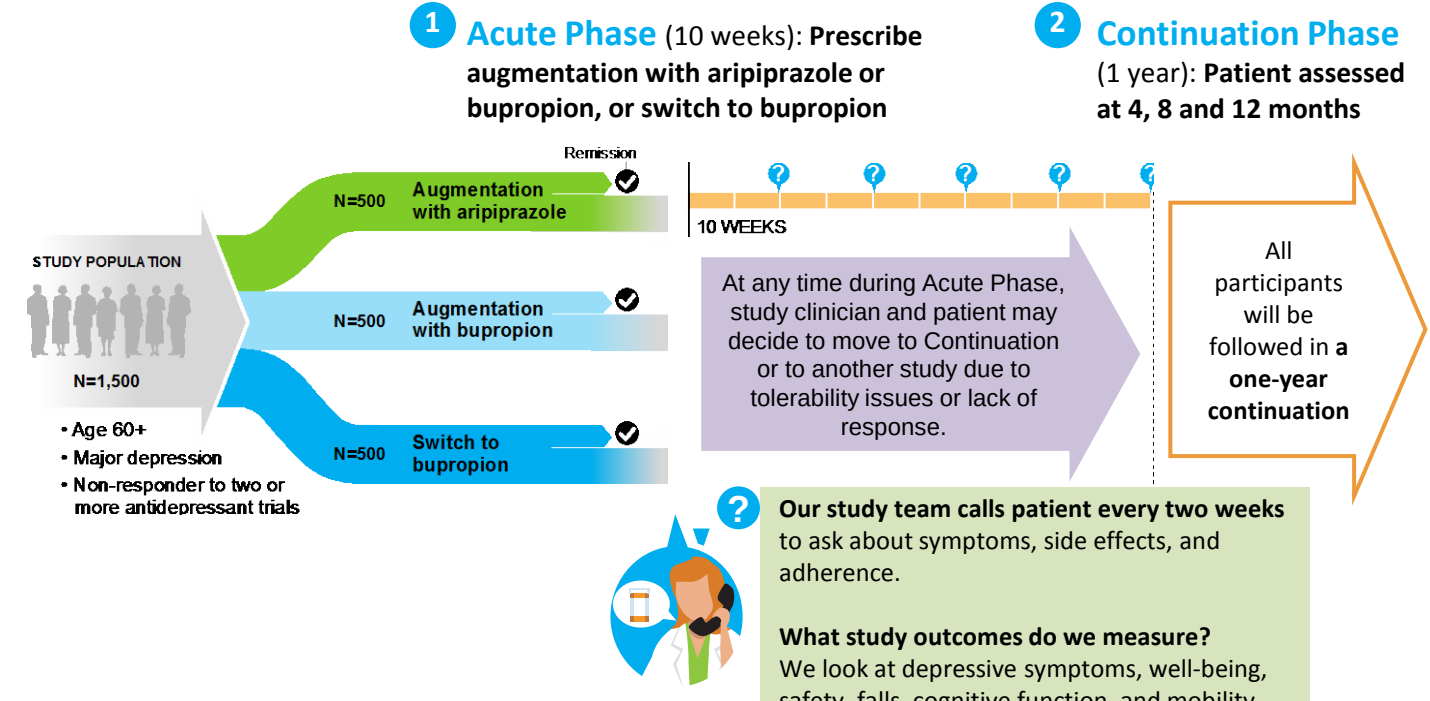
Toronto is one of five OPTIMUM sites.



You are at the center of this study!

- **Patients** stay with their own provider.
- **Provider** prescribes medication.
- **Study team** guides treatment steps.

OPTIMUM Study Design



What are we measuring?

Research team does the study measurements. We look at symptomatic remission, well-being, safety, falls, cognitive function, & mobility.

Who is eligible for OPTIMUM?

Inclusion

- Age 60 or older
- Treatment Resistant Depression, defined by:
  - Major depression
  - PHQ-9 = 6 or greater
  - Two or more failed trials of antidepressant meds

Exclusion

- Dementia
- Unstable medical illness
- Unable to take any of the OPTIMUM medications

If uncertain a patient is eligible, refer them to us, and we'll sort it out. We offer informal consults, including if your patient would benefit best from OPTIMUM or another treatment.

Patient Health Questionnaire to screen and monitor depressive symptoms

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Column Totals		_____ +	_____ +	_____
Add Totals Together		_____		

- A score of 6 or higher determines eligibility.
- Persistent scores of 6 or higher indicate a need for medication adjustment.

How OPTIMUM Works

1 How do I refer my patients?

Contact us to refer your patients.
We'll screen your patients and let you know when yours is eligible.

2 What can I expect?

We will ask you to prescribe a study medication at a specific dose. **You prescribe it.**

3 How is the medication managed?

We'll call your patient every two weeks to ask them about their symptoms and side effects. We then recommend that you raise or lower the dose, stay the course, or stop the medication. This partnership provides measurement-based collaborative care to your patients.

4 What if the patient has a side effect or other problem?

Report it to us; we will follow-up. The study psychiatrists can provide clinical recommendations to you and your patient based on safety labs and drug monitoring.

5 How will we be compensated for our time?

Participants will be compensated $60 for the initial screening visit and $30 for each assessment visit after that. Clinicians will also receive compensation for their time.

Getting Started

- Providers who are interested will go through an informed consent process
    - See OPTIMUM Provider Informed Consent Form
- Should you agree to participate, you will sign an informed consent form and will become a participant in the study (more on this later)
- After this, we may begin working with your patients

What is in it for you and your practice?

- More **effectively treat** depressed older patients.
- Learn **state-of-the-science** prescribing practices.
- Receive **regular decision support** from geriatric psychiatrists that is specific to each patient.
- Receive **treatment recommendations** and mental health referrals for ineligible patients.
- This study is a true partnership: **we pay you or your practice** for your added time and effort.

Prescribing Information

Aripiprazole augmentation	
Starting Dose:	2.5 mg
Target Dose:	7.5 mg to 10 mg
Maximum Dose:	15 mg
Titration:	Study team recommends increases every two weeks (5, 7.5, 10, 15mg) based on symptoms and tolerability.
Potential Side Effects:	-Akathisia, or restlessness is a common side effect (~30% of patients). Usually this is mild and managed by reducing the dose -Other less common side effects: insomnia, fatigue, blurred vision, somnolence, tremor, constipation, sedation, and dizziness. -Can cause weight gain; usually this is mild. Rarely, may increase blood sugar, cholesterol or triglycerides. -As an antipsychotic, aripiprazole can cause parkinsonism (usually very mild), tardive dyskinesia, and even neuroleptic malignant syndrome (high fevers, muscle rigidity, altered mental status, irregular pulse or blood pressure, rapid heart rate, excessive sweating, and heart arrhythmia).
Safety labs and Monitoring:	-CBC, electrolytes, liver function tests, TSH, B12 within the last 6 months -Fasting blood glucose and lipid profile within the last 6 months and as often as clinically necessary. We'll recommend when these are needed. -ECG within last 12 months

Bupropion switch and augmentation

Starting Dose:	150 mg (We will recommend an appropriate taper from current antidepressant for switch strategy prior to initiating bupropion)
Target Dose:	300 mg
Maximum Dose:	450 mg – case by case basis
Titration:	We will recommend increase to 300mg after four weeks based on symptoms and tolerability.
Potential Side Effects:	-Stimulant –like effects: anxiety, headache, increased heart rate, insomnia, decreased appetite. -Adrenergic side effects: Excessive sweating, dry mouth, dizziness, tremor, constipation, nausea, high blood pressure, increased urination. - Unsteadiness when walking (rare). -Seizures may occur in 0.4% of patients receiving bupropion. We keep the dose low, and exclude patients with seizure disorder.
Safety labs and Monitoring:	-CBC, electrolytes, liver function tests, TSH, B12 within the last 6 months -Monitor for side effects.

Watching out for our patients

Federal legislation **protects human subjects** in research

Research MUST respect privacy and confidentiality:

As part of consent, we ask patients to sign a **HIPAA authorization** that is required before disclosing PHI for research.

HIPAA contains specific rules for research that allow:

- You to disclose names and contact numbers to us in a referral.
- Us to screen records to find potentially eligible patients.

Research MUST be ethical. Three principles we all must follow:

Beneficence: We are obligated to minimize risks and maximize benefits for participants.

Justice: Risks are commensurate with benefits for all participants

Respect for persons: Patients have the choice to enter and leave the study. We must ensure they understand the study before making choices about participating.

The process is designed to protect the patient. Terms to know:

Human subject: your patients in this study; that is, anyone who signs an OPTIMUM consent form.

REB: Research Ethics Board (part of CAMH) is a group of scientists and lay persons who review research to ensure it is not unduly dangerous.

Informed consent: your patient's formal agreement to participate based on a thorough understanding of the study.

Study bolsters patient care

This research adds to usual clinical care:

- Participants receive new treatment options.
- Study results can help in the care of other patients.

Oversight boards help protect the interests of participants, and each person in the study – you, me, all research staff – is responsible for patient protection and ethical conduct in the study.

Study questions or concerns?

www.OPTIMUMstudy.org

TOGETHER, WE CAN FIND A BETTER TREATMENT

To refer a patient call local OPTIMUM Recruitment Line:

1-866-539-3510
optimum@camh.ca

Medical questions about study patients and treatment:

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