

OPTIMUM A: Optimizing Outcomes of Treatment-Resistant Depression in Older Adults A

A pragmatic study:

- Comparing risks and benefits of different treatment options in real world clinical settings
- For older adults whose depression has not improved with first line treatment

A large scale study:

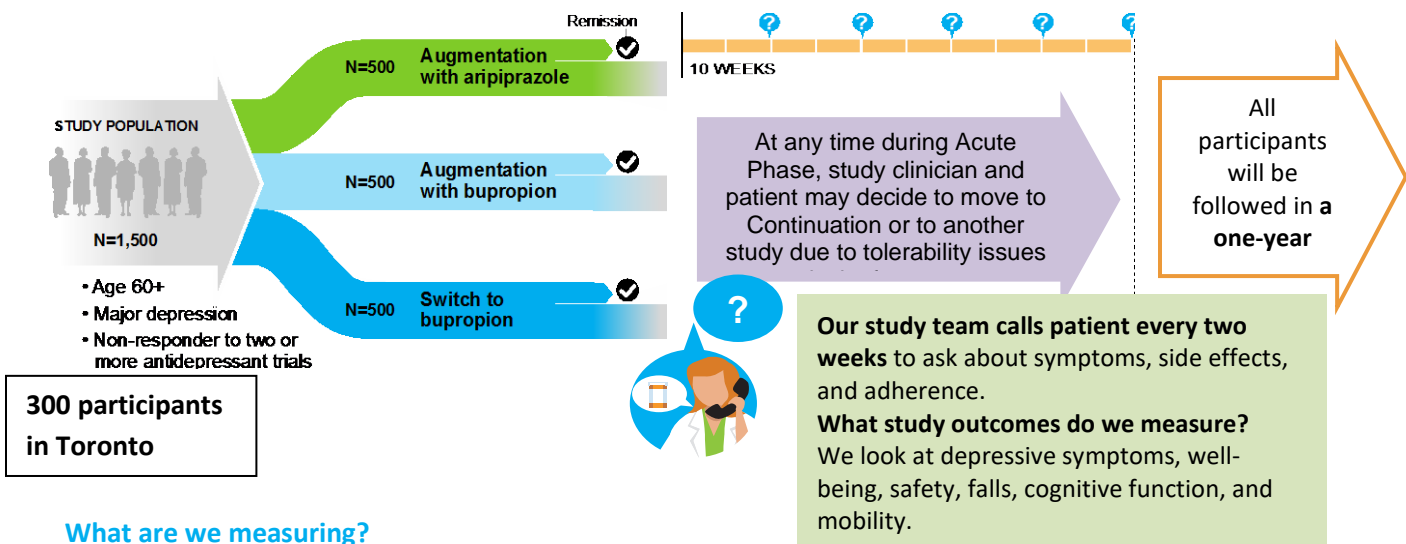
- Our academic partners include medical researchers at the University of Pittsburgh, Columbia University, the University of California, Los Angeles, and the Centre for Addiction and Mental Health in Toronto.
- By partnering with you and other providers, we aim to enroll 1,500 older adults in the study

Our goal is to support you in providing excellent care to your patients with treatment-resistant depression:

- *During the study* – We will check in with participants often, keep you updated on their progress, and make evidence-based medication recommendations.
- *In the future* – With your help, we will fill a major gap in the evidence and provide clinicians with new information to provide optimal care to older adults.

OPTIMUM A Study Design

- 1 Acute Phase (10 weeks):**
Prescribe augmentation with aripiprazole or bupropion, or switch to bupropion
- 2 Continuation Phase (1 year):** Patient assessed at 4, 8 and 12 months



What are we measuring?

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

OPTIMUM A Inclusion criteria:

- a) Men and women aged 60 and older, with equal proportions aged 60-70 and 70+.
- b) Current Major Depressive Disorder (MDD), single or recurrent, as diagnosed by DSM-5 criteria.
- c) Failure to respond adequately to two or more antidepressant treatment trials of recommended dose and length (at least 12 weeks).
- d) PHQ-9 score of 6 or higher.

OPTIMUM A Exclusion Criteria:

- a) Inability to provide informed consent.
- b) Dementia, as defined by Short Blessed >10 and/or clinical evidence of dementia. Patients screened out due to possible dementia may be referred to a local memory clinic or back to their clinician for evaluation to clarify the presence or absence of dementia.
- c) Lifetime diagnosis of bipolar I or II disorder, schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder, or current psychotic symptoms, as diagnosed by the MINI. A recommendation for psychiatric referral will be made in these cases.
- d) High risk for suicide (e.g., active SI and or current/recent intent or plan) and unable to be managed safely in the clinical trial (such as unwilling to be hospitalized). Urgent psychiatric referral will be made in these cases.
- e) Contraindication to proposed study medications, as determined by study physician including history of intolerance or non-response to proposed medications.
- f) Non-correctable, clinically significant sensory impairment (e.g., cannot hear well enough to cooperate with interview).
- g) Unstable medical illness, including delirium, uncontrolled diabetes mellitus, hypertension, hyperlipidemia, or cerebrovascular or cardiovascular risk factors that are not under medical management. This will be determined based on information from the patient's personal physician's and study physician clinical judgement. Referral to the patient's personal physician or to a general practitioner will be made in these cases.
- h) Moderate to severe substance or alcohol use disorder, as determined by study physician. Referral to appropriate treatment will be made in these cases.

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