

Toronto, Ontario,  
Canada

# OPTIMUM: OPTIMIZING OUTCOMES OF TREATMENT-RESISTANT DEPRESSION IN OLDER ADULTS

Operationalizing a multi-centre pragmatic randomized controlled trial with family doctors and psychiatrists.

K. Fitzgibbon<sup>1</sup>, R. Campbell<sup>1</sup>, A. Perivolaris<sup>1</sup>, B. H. Mulsant<sup>1,2</sup>, A. Flint<sup>2,3</sup>, D. Blumberger<sup>1,2</sup>, C. Mulder<sup>4</sup>, P. Selby<sup>1,5</sup>

1: Centre for Addiction and Mental Health, Toronto, ON; 2: University of Toronto, Department of Psychiatry, Toronto, ON; 3: University Health Network, Toronto General Hospital Research Institute, Toronto, ON; 4: Association of Family Health Teams of Ontario, Toronto, ON; 5: University of Toronto, Department and Family and Community Medicine, Toronto, ON.

## Abstract

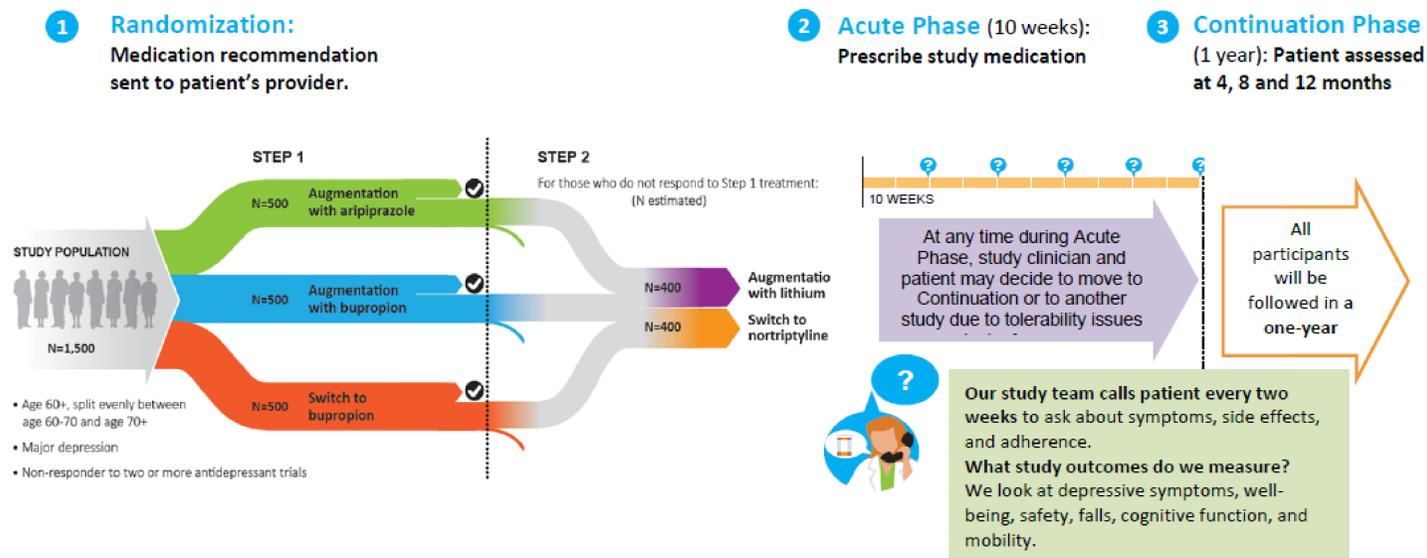
**Statement of Purpose:** Treatment-resistant depression (TRD) is a major health problem for the aging population: in most older adults, depression fails to remit with first-line antidepressant pharmacotherapy. Older adults with persistent depression experience significant medical consequences, place high burdens on caregivers, and suffer high suicide rates. Making it worse is the paucity of evidence-based treatments at a stage in life when medications benefit vs. risk ratio is crucial.

OPTIMUM is a five city (4 US and 1 Canadian) study that will use both quantitative and qualitative methods. It includes a pragmatic, adaptive randomized controlled trial (RCT) to evaluate the comparative benefits and risks of antidepressant strategies (augmentation versus switching medications) and how aging changes this balance of benefits and risks.

**Methods:** OPTIMUM will randomize 1500 older adults aged 60+ to 10 weeks of one of three treatment strategies: aripiprazole augmentation, bupropion augmentation, or switch to bupropion. Participants who complete acute treatment will be followed for one year. This pragmatic RCT will be carried out in real-world primary care clinical settings and psychiatric clinics in Ontario. Primary care providers will provide treatments, with decision support from the study team. Stakeholder engagement including patients and professional or family caregivers will ensure the study methods and results are relevant to both patients and providers.

## Study Design

The OPTIMUM study will use both quantitative and qualitative methods. It includes a pragmatic, adaptive randomized controlled trial (RCT) to evaluate the comparative benefits and risks of antidepressant strategies and how aging changes this balance of benefits and risks.



### What are we measuring?

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

## Discussion: Engagement and Recruitment

The real world nature of the OPTIMUM study, in addition to the criteria necessary to qualify as treatment-resistant, has led to various challenges in the implementation of the study.

### Challenge: Engagement with Primary Care

- Difficulties finding PCPs to participate
- PCP concerns regarding workload

### Challenge: Patient recruitment

- Specific criteria for TRD
- Prevalence of exclusion criteria in patients
- Prevalence of patients who have previously failed two adequate medication trials

### Challenge: Clinical Trials Ontario process

- Learning the new multi-centre process

### Strategies to increase engagement and recruitment:

- Engaging with established PCP networks
- Phone meetings with FHTs, CHCs, NP clinics
- Site visits to further describe study details
- Collaborating with existing primary care organizations

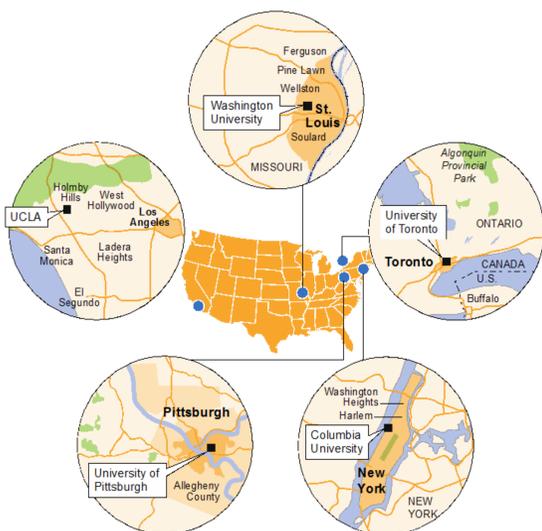
## Conclusion

Implementing pragmatic studies in primary care require attention to a variety of barriers and enablers.

The OPTIMUM study has been faced with difficulties relating to creating partnerships with PCPs and family health teams, as well as difficulties recruiting participants due to barriers to engaging within this sector.

Stakeholder engagement, especially from PCPs, may provide relevant strategies to increase partnership with primary care, therefore increasing patient enrollment.

## Study sites



## Project Timeline

