OPTIMA

Optimizing Patient Centered-Care: A Pragmatic Randomized Control Trial Comparing Models of Care In the MAnagement of Prescription Opioid Misuse

WHAT IS CRISM ?

The Canadian Research Initiative in Substance Misuse (CRISM) is Canada's only dedicated research network for substance use interventions in building national and regional infrastructure for clinical, health services, and population health research in substance use and addictions.

OPTIMA TEAM

Steering Committee

CRISM Nominated Principal Investigators (NPIs), Dr. Julie Bruneau, Dr. Benedikt Fischer, Dr. Cameron Wild and Dr. Evan Wood, will act as the Steering Committee that will be consulted as needed to provide oversight and high-level direction from a research perspective. **Dr. Bruneau**, NPI for the QM Node, has been designated as the Chair of the Steering Committee. The Lead Regional Principal (Lead RPI) Investigator will also join this committee.

Regional Principal Investigators

British Columbia Node
Eugenia Socias, MD & Keith Ahamad, MD

Prairie Node
Ron Lim, MD

Ontario Node
Bernard Le Foll, MD, PhD

Quebec-Maritimes Node
Didier Jutras-Aswad, MD, MSc (Lead RPI)

Dr. Didier Jutras-Aswad, has been designated by the Steering Committee as the Lead RPI, responsible for overall trial implementation and for providing oversight at a national level, as well as for initiating and ensuring regular communication with RPIs.

National Research Coordinator
Jill Fikowski, MPH

Medical Monitors

British Columbia Node
Scott MacDonald, MD

Prairie Node
Avininder Aulakh, MD

Ontario Node
Bernard LeFoll, MD

National & QM Node
Suzanne Brissette, MD

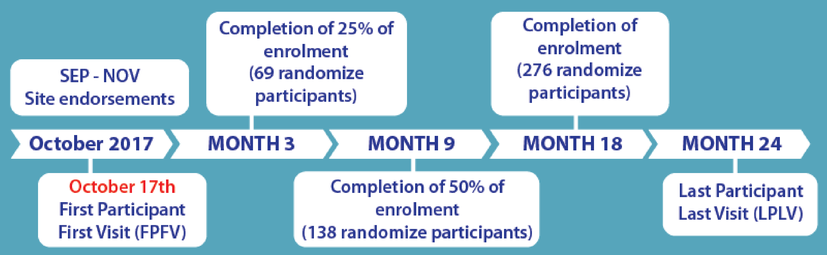
Regional Study Coordinators

British Columbia Node
Katrina Blommaert, MPH

Prairie Node
Denise Adams, PhD

Ontario Node
Jose Trigo, PhD

Quebec-Maritimes Node
Amel Zertal, MSc

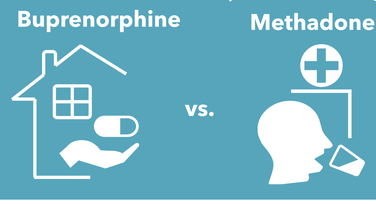


CRISM-ICRAS
Canadian Research Initiative in Substance Misuse
Initiative Canadienne de Recherche en Abus de Substance

IRSC CIHR
Instituts de recherche en santé du Canada
Canadian Institutes of Health Research

OBJECTIVES

- Compare and evaluate effectiveness of two models of opioid agonist treatment in real-life clinical practice settings :



ADDRESSING RESEARCH GAPS :

- Randomized controlled trials evaluating opioid agonist treatments are done almost exclusively among heroin users
- There is a lack of study comparing buprenorphine/naloxone vs. methadone in real-world setting according to each drug safety profile
- Long-term opioid agonist treatment (e.g. > 6 months) is accessed by fewer than 10% of individuals with opioid use disorder

PRIMARY HYPOTHESIS

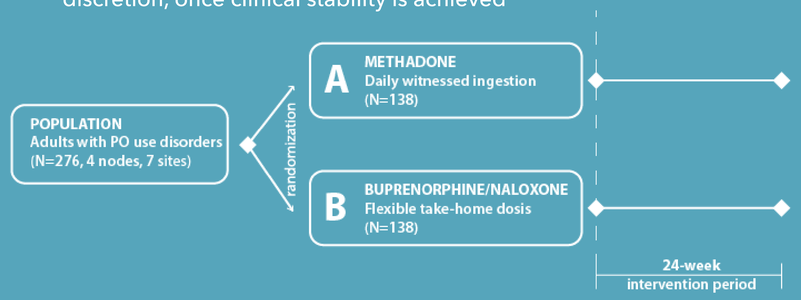
Buprenorphine/naloxone flexible take home dosing is non-inferior to **methadone** standard model of care in treating prescription opioid use disorder, as measured by the mean percentage of opioid-free urine drug screens during 24 consecutive weeks

STUDY DESIGN

Participants will be randomized to receive either:

a) **Methadone** provided via initial daily witnessed ingestion as per local guidelines

b) **Buprenorphine/naloxone** maintenance therapy provided via flexible take-home dose regimens dispensed as per the physician's discretion, once clinical stability is achieved



DURATION

Up to 28 weeks, including a 24-week intervention period and up to 4 weeks for randomization

Research visits take place every 2 weeks (including collection of urine samples) for the 24-week intervention period

Clinic visits take place at physician discretion or as needed by the participant

7 clinical sites across Canada

- Multi-centered
- Open label
- 2 arm
- Randomized trial
- N = 276

INCLUSION CRITERIA :

- 18-64 years
- Meet DSM-5 criteria for Prescription Opioid Use Disorder which requires opioid agonist therapy
- Willing to access a substitution treatment
- If female of childbearing potential, willing to practice effective birth control

EXCLUSION CRITERIA :

- Serious medical, mental health or other substance use disorder making participation hazardous
- Heroin reported as most frequently used opioid
- Currently pregnant/breast feeding
- Current prescription with medications that may interact with study medications

ANCILLARY STUDIES :

- **Ancillary study 1:** Take Home Naloxone Survey : Compare THN programs awareness, uptake, and use at the national level
  Dr. Katherine Rittenbach (Principal Investigator)
  Dr. Elaine Hyshka (Co-Investigator)
  Dr. Carla McLean (Co-Investigator)
- **Ancillary Study 2:** Patient Experience Study : Examines trial-specific, individual, social influences on protocol adherence and completion
  Dr. Lindsey Richardson (Principal Investigator)
- **Ancillary Study 3:** Pharmacogenomics Study : Assess the correlation between genetic variants and treatment response
  Dr. Bernard LeFoll (Principal Investigator)
  Dr. Rachael Tyndale (Co-Investigator)
- **Ancillary Study 4:** Cost-Effectiveness Study : Determine the response in HRQoL to treatment, identify health determinants and social costs, compare buprenorphine/naloxone and methadone
  Dr. Bohdan Noysk (Principal Investigator)
  Dr. David Whitehurst (Co-Investigator)
- **Ancillary Study 5:** Sexual Functioning Study : Compare BUP/NX and methadone regarding sexual dysfunction in men and women, and determine its impact on treatment attrition.
  Dr. Sherry Stewart (Principal Investigator)
  Dr. Natalie Rosen (Co-Investigator)
  Dr. Amanda Hudson (Co-Investigator)

OUTCOME MEASURES :

Primary outcome measure

- Opioid use

Secondary outcome measure

- Retention
- Adherence
- Safety
- Treatment satisfaction
- Patient engagement