

# Indigenous Clinical Trial Research

*Insights, Opportunities, and the Path Forward:  
A Dialogue*

# Clinical Trial (Demonstration Project)

This feasibility study evaluates the integration of traditional country foods and Elder-led wellness practices into clinical care. Conducted in Arviat, Nunavut, with 40 participants, the trial measures depression and anxiety through PHQ-9 assessments and guided conversations. Objectives include testing feasibility, cultural acceptability, and health impact, and addressing systemic barriers to food sovereignty. Results aim to strengthen cultural identity, resilience, and inform policies that embed culturally relevant, community-driven mental health practices across Inuit Nunangat (homeland).

# Study Purpose & Hypothesis

- IQ-guided trial to reduce depression
- Country foods & Elder-led wellness
- Primary: feasibility, acceptability, PHQ-9 impact
- Secondary: identity, cohesion, policy barriers
- More country foods → lowers depression

# Significance Ethics & Outputs

- Restores food sovereignty; supports self-determination
- REB & NRI license; trauma-informed consent
- PIs: Clark, Tagalik; Kimble, Weleff, McDonald
- Deliverables: papers, briefs, community reports, workshops

# Design & Measures

- Arviat, NU; n=40; 97 days
- Immediate vs delayed; 3 phases
- Dose tiers: >80%, 40–80%, <40%
- PHQ-9: baseline, Day 60/90/97
- Mixed-effects models; REDCap collection and analysis

# **Building Capacity and Healing Through Psychedelic-Assisted Therapy:**

## ***A Heal the Healer Program and Randomized Control Trial for Health Providers who work with Indigenous people***

Waitlist-controlled randomized controlled trial with therapists and clinicians (n=20).

Preparation then four-step healing model:

1. **Bonding, Connecting, and Learning**
2. **Ceremony, Medicine, and Healing:** therapeutic dose of psilocybin
3. **Self-care**
4. **Integration and Reconnecting:** one-month, six-month follow-up

### Study Team

Dr. Wanda Phillips-Beck, FNHSSM - PI  
Dr. Taylor Morriveau, FNHSSM - PI  
Dr. Shelley Turner, Ekosi Health - PI  
Dr. Zach Walsh - UBC - PI

Kira Regan, Licensed psychotherapist and Certified EMDR Therapist  
Dr. Tracie Parkinson (Ph.D., C. Psych.) - PI  
Carla Pauls, MC, PhD(c) - PI

# Study Purpose & Hypothesis

- **Culturally appropriate clinician training** for psychedelic therapy integrating Anishinaabe/Cree healing practices. Prepares clinicians to provide more effective care for Indigenous populations.
- **Primary:** clinician empathy, cultural competence, and self-reported healing.
- **Secondary:** therapeutic alliance capabilities and self-awareness.
- Greater empathy, reduced burnout and self-reported healing/wellness compared to controls. Readiness to treat Indigenous patients with PTSD and addictions.

# Preparatory Work and Tápwewin

- **Feasibility:** Traditional medicines, structural barriers, regulations
- **Data Sovereignty:** Operationalizing OCAP®
- **Outcomes:** Lack of quantitative tools for Indigenous health
- **Ethics:** Institutional and First Nations
- **Collaboration:** National Collaborating Centre for Indigenous Clinical Trials
- **Relational Accountability:** Respect, Relevance, Reciprocity, Responsibility, and Refusal
- **Acknowledging Harm:** Legacy of colonial harms in clinical trial research



# **Preparatory Work and Tápwewin**

- 1. Centre Indigenous Leadership and Sovereignty**
- 2. Adopt Rights-Based and Liberatory Approaches**
- 3. Support Community-Led Research**
- 4. Promote Education and Accountability**