Ketamine-assisted Psychotherapy within a Roots to Thrive Community of Practice: Building a Strong Foundation

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We are in the midst of an international mental health crisis, with healthcare providers at even greater risk for mental distress. Workplace stress can lead to burnout, PTSD, and treatment resistant depression (TRD) which affects morale, absenteeism, retention, and patient care. The mental health of healthcare providers is understudied and inadequately supported, especially given the current pandemic. This program of research seeks to support the development of an innovative mental health intervention in response to the mental health challenges that have been further compounded by COVID-19. The initial focus is to address PTSD and TRD among healthcare providers with a combination therapy involving an evidence-informed resilience integration program, Roots to Thrive (RTT) communities of practice (CoP) with Ketamine-assisted Psychotherapy (KAP). In recent pilots, the RTT CoPs demonstrated a significant impact on wellness traits and cognitive control of the participants. Ketamine has been described as the single most important advancement in the treatment of depression in over fifty years. When given intramuscularly, ketamine has psychedelic affects, which loosens rigid mental constructs and defense structures, promoting an opportunity to heal. The foundation of this program is to leverage the experience of belonging in community to cultivate a greater ability to heartfully connect to self, spirit, and community itself. KAP is then applied as a supportive adjunct to address barriers to connection (trauma responses, destructive belief systems). We aim to capitalize on the synergy of these two interventions to provide a novel, evidence-based intervention for PTSD and/or TRD. We are now developing this combined program in collaboration with policy makers, researchers, clinicians who have experience with this treatment, and patient partners (healthcare providers with PTSD or TRD). Beginning with healthcare providers in need, our team will create, implement, and study this novel intervention for PTSD and/or treatment resistant depression. In the long-term, this program of research enables us to also develop an RTT-MDMA-assisted therapy protocol (available in 2021 for medical use) and to provide a roadmap for other public entities to take up psychedelic-assisted therapies to address treatment resistant PTSD and TRD.

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We are in a mental health crisis. Nearly half of all Canadians have or have had a mental health diagnosis by the age of 40 (CMHA, 2020a). Current treatment modalities only work for a minority of those suffering from chronic mental distress. Healthcare providers (HCPs) are at especially high risk of burnout, Post-Traumatic Stress Disorder (PTSD) and Treatment Resistant Depression (TRD). In areas recovering from the first wave of the COVID-19 pandemic, evidence of the mental health toll on frontline HCPs is emerging (Lai et al., 2020; Tsamakis, et al., 2020; Xiao et al., 2020). Many are struggling to find their footing in their work and life roles as the first wave of the outbreak subsides. Tragically more than 600 nurses worldwide have now died from the virus (CBC News, 2020) and due to mental anguish, some have taken their own lives. The SARS epidemic in 2003 left high risk frontline care providers with long term anxiety, PTSD and depression (Maunder et al, 2006; McAlonan et al., 2007) and the outlook for HCPs treating COVID-19 patients is worse. Compounding the inherent stress of an international outbreak, is an existing crisis of mental health disease in HCPs and woefully ineffective treatment methodologies for most sufferers of PTSD and TRD (O'Leary, Dinan, & Cryan, 2015).

Pre-pandemic, HCP Mental Health: More than 50% of Canadian HCPs working in acute care areas were suffering from mental health conditions caused or exacerbated by the toll of their high stress, often trauma-prone careers. In 2016, nurses submitted 12% of Worksafe BC mental health claims despite being only 2% of the province's workforce (BCNU, 2019; CIHI, 2018); a formal strategy was launched to address the 52-64% of HCPs suffering from emotional exhaustion, critical incident stress or PTSD (MNU, 2015); and the CMA's National Physician Health Survey found that 49% of medical residents, and 33% of physicians, screened positive for depression, while 38% of residents and 29% of physicians screened positive for burnout (Simon & McFadden, 2017). Indeed, between 40% and 60% of HCPs will face burnout at some point in their career (Olson et al., 2015; Rabb, 2014). The ultimate cost of unmanaged mental illness among HCPs is patient safety because unhealthy HCPs often work short staffed, exhibit compassion fatigue, and are at increased risk of job error. Additionally, up to 30-57% new graduate nurses leave the profession within two years, usually because of PTSD, depression, or moral distress (ARNBC, 2017; Chandler, 2012; Laschinger et al., 2010). Consequently, as approximately 70% of healthcare costs go toward human resources (BC Ministry of Health, 2014), the financial implications of the crisis are enormous (Bodenheimer & Sinsky 2014). In the context of the COVID-19 pandemic the health and financial risks are even greater. Therefore, interventions that support the mental health of HCPs are imperative (Tsamakis et al., 2020).

Enduring Medical Outbreaks and HCPs: Lai et al. (2020) examined 1257 Chinese HCPs (physicians and nurses) directly working to diagnose, treat and care for COVID-19 patients. They found that >50% screened positive for depression, 44% for anxiety, 33% for insomnia and 71% for distress, with the psychological burden more severe for women and nurses, and those from Wuhan, China the epicenter of the outbreak, when compared to those in other regions of the country. Similarly, in the aftermath of the first wave, clinicians in Greece are experiencing psychological distress (Tsamakis, et al., 2020). There are parallels between COVD-19 and the 2003 SARS outbreak, with health workers who worked in high-risk clinical settings or who had family or friends impacted by SARS exhibiting significantly higher levels of PTSD (Wu et al.,

2009). Factors that contribute to COVID-19 related distress and psychological comorbidities such as PTSD and TRD include: Emotional strain and physical exhaustion when caring for growing numbers of acutely ill patients of all ages who have the potential to deteriorate rapidly, caring for coworkers who may become critically ill and sometimes die from COVID-19, shortages of personal protective equipment (PPE) that intensify fears of coronavirus exposure at work, concerns about infecting family members from workplace exposures, shortages of crucial medical equipment, anxiety about assuming new or unfamiliar clinical roles and expanded workloads in caring for patients with COVID-19, and limited access to mental health services for psychological distress (Ayanian, 2020).

Finally, the World Health Organization (WHO, 2020) just released recommendations to improve global health by investing in the world's nurses. Roots to Thrive (RTT), developed by Dr. Dames in 2018 with the support of *a Michael Smith Foundation for Health Research REACH Grant*, is built on a framework that works through communities of practice (CoP) and experiential education to address the WHO recommendations by promoting integrated and holistic healthcare, addressing staffing shortages by reducing burnout and strengthening leadership by cultivating self-actualized and empowered HCPs.

PROJECT AIMS AND INTERVENTIONS

In collaboration with Island Health (IH) clinicians, therapists, academics, decision makers, Elders, and HCPs with lived experience of PTSD/TRD from across British Columbia (BC), my team has developed a cutting edge integrated approach for the treatment of HCP mental illness. This approach combines an evidence-informed community of Practice (CoP) framework – Roots to Thrive (RTT) with Ketamine-Assisted Psychotherapy (KAP). While each treatment alone has shown good results, the efficacy of the programs as duos in conjunction and as a whole is not known. Building on the academic and clinical experience gained when developing and testing these approaches, my team is now moving forward, paving the way for BC to become a national leader in the development and implementation of these innovative and desperately needed treatments. As we continue to synthesize knowledge in preparation for KAP-RTT program implementation, my team is now ready to prepare to operationalize within an 'already approved' quality improvement framework. We are running the program through the QI framework, modifying the protocol according to the results and then the MSFHR funds will make it possible to continue in a program of research, where we will explore impacts by running six cohorts (12 people per cohort) through a mixed methods wait list control study. This work will not only address my project aims but also create a sustainable community-based treatment model that will lay the groundwork for other promising psychedelic medicines currently in the final stages of Health Canada and FDA approval. Dr. Haden, the Executive Director for the Canadian Multidisciplinary Association for Psychedelic Studies (MAPS) predicts that MDMA will be approved to treat PTSD by the FDA and Health Canada by 2021 (Banks, 2019). We plan to use what we have learned to modify and expand our community-based treatment model to include another medicine adjunct (MDMA), and then develop and study the combined protocol (now MDMA-RTT) again.

Intervention Details – Ketamine Assisted-Psychotherapy (KAP). KAP: Ketamine is an FDA-approved drug mainly used as an anesthetic in high doses. When ketamine is administered in sub-anaesthetic doses, as a NMDA receptor antagonist, it produces a phenomenological psychedelic effect similar in some ways to psilocybin and Lysergic acid diethylamide (LSD) (Tupper et al., 2015), enabling therapists to help people work with and through the belief systems and emotions associated with trauma. Ketamine is now a well-established treatment for mood disorders, but is largely given intravenously with minimal psychotherapy follow-up (Grady et al., 2018). More recently ketamine's psychedelic effects are showing benefits for patients with a variety of diagnoses when combined with psychotherapy. It is used off-label to treat PTSD and TRD and is described as the single most important advance in the treatment of depression in over fifty years (Duman & Aghajanian 2012; Feder et al., 2014; Fond, 2014; McGirr, 2015; Kishimoto, 2016; Krystal et al., 2019). Recent findings from a study of three large KAP clinics demonstrated that KAP was an effective method for decreasing depression and anxiety,

especially for those with severe symptom burden (Dore et al., 2019); however long-term studies are limited. Not only do ketamine and other psychedelics show enormous promise in alleviating mental distress, but the cellular effects of these medicines promote beneficial and potential curative structural and functional neuroplasticity (Ly et al., 2018).

Recent advances in psychology and psychopharmacology demonstrate the protective role of resilience against developing PTSD (Mealer, Jones & Moss, 2012; Mealer et al., 2017; Onvedire et al., 2017; Osenbach, 2014). Mealer et al. (2017) underscore the need to tailor resiliency training to HCPs at greatest risk for PTSD. The ketamine/brain-behavior relationships implicated in PTSD and TRD are well supported and scientists suggest that the therapeutic effects of ketamine are potentiated by enhancing resiliency-integration therapies (Brachman et al., 2016; Krystal et al., 2017; McGowan et al., 2017).

My team will modify current Island Health (IH) practices. They are already administering intravenous (IV) ketamine for mood disorders. Their current method does not benefit from the psychedelic ('mind manifesting') affect, a community of support or follow up psychotherapy to integrate and sustain meaningful improvements. Our integrated KAP-RTT program, delivered in a group/community-based format, will incorporate all of the holistic aspects required to facilitate and sustain healing and it will build the capacity to include other psychedelic-therapy adjuncts as they soon become legal (Banks, 2019). It also removes treatment from an operating room setting, where it is fiscally infeasible to treat more than a few acute patients.

Intervention Details - Roots to Thrive (RTT) Communities of Practice (CoP). In Roots to Thrive (RTT), Dames (2018) describes resilience as an ability to adapt in the face of adversity. RTT aims to promote personal resilience and thriving within ongoing communities of practice (CoP) undergirded by Polyvagal Theory (Porges, 2011), Congruence (Rogers, 1959), and Sense of Coherence (Antonovsky, 1979).

> ***Communities of practice (CoP)**: a group of people who share an intention for something they do and learn how to do it better as they interact regularly (Wenger-Trayner, 2015).*
> ***Roots to Thrive (RTT) Communities of practice**: a group of people with a shared intention to cultivate a space of unconditional positive regard, aiming to minimize stress and other barriers to thriving and to maximize one's ability to flourish individually and in community. As a group, they facilitate the ability to operate from this place in their day to day lives through relationships and practices that expand awareness, promote self-regulation/stress mitigation, heartful connectedness, and an ability to live one's calling (Dames, 2020).*

Group therapy (delivered in RTT as a community of practice), as opposed to individual therapy alone, can have a significant positive impact on one's ability to be witnessed in their development of news insights and ways of being and to then integrate these meaningful shifts in their day to day lives (Dames, 2020; Porges, 2011; Yalom, 1995)

The RTT program includes 12 weekly sessions that develop stress management and resilience skills within a community of practice (CoP) that prioritizes self-expression and connection. For the KAP-RTT prototype development, CoP's will include 12 healthcare professionals with treatment resistant PTSD or TRD from varying locations and disciples. Because of a media release and word of mouth, we quickly filled a waiting list of healthcare providers eager to contribute to and participate in the program. Within these 12 weeks, participants will receive three KAP sessions (space and pharmacy services provided by IH). By engaging participants in CoPs that exemplify unconditional positive regard and that practice regulation and self-actualization, participants experience attachment and gain resilience.

> ***Unconditional Positive Regard:** To accept the person for what he or she is. Positive regard is not withdrawn if the person makes a mistake. In this space, people feel freer to try things out, despite the risk of missteps (Rogers, 1959). It's not about liking each other or accepting behaviours, it's about respecting one another as human beings with free will and operating under the assumption that they are doing the best they can with the tools they have (Dames, 2020).*

RTT's first research trial was conducted with the leadership team at the Nanaimo Regional General Hospital (NRGH) in recognition of the need to provide resilience training for the hospital's front line managers and senior administrators. Small scale RTT trials are ongoing and each session's evaluation informs the curriculum. RTT participants have so far reported reduced stress, improved co-worker relationships, and frequent moments of thriving (Dames et al., unpublished data). In another RTT pilot, we studied brain wave impacts using electroencephalography in a group of 16 participants, which showed significant impacts on brain activity that correlates with cognitive control (Dames et al., unpublished data). Unfortunately, a RTT program for VIU employees this spring was cancelled due to COVID-19. That said, RTT is running virtually in a community setting with the support of philanthropist funding – aiming to mitigate the mental health impact of COVID-19 on vulnerable populations.

The mechanism of action between ketamine and the brain-behaviour relationships implicated in PTSD and TRD is well supported (Brachman et al., 2016; Krystal et al., 2017; McGowan et al., 2017). Recent advances in psychology and psychopharmacology have shown that resilience can be preventative for PTSD and further that the therapeutic effects of ketamine may be potentiated by enhancing it with resiliency-based communities of practice (Mealer, Jones & Moss, 2012; Mealer et al., 2017; Onyedire et al., 2017; Osenbach, 2014). Most KAP treatment protocols do not provide resilience development and long-term peer support. This RTT component of our therapy protocol is novel and designed to strengthen KAP treatment efficiency.

With the current need and largely ineffective traditional treatment methods, my team has developed an innovative connection-centred mental health strategy. We have developed it, and now we have the opportunity to implement it, adapt it, and conduct evaluation research to share the findings broadly. We begin the knowledge synthesis process (supported by a CIHR Knowledge Synthesis grant in May 2020) by developing and testing the combined KAP-RTT protocol (12 weeks of CoP with 3 KAP sessions embedded). The larger program of research will examine the efficacy of the program using a mixed methods wait list control design. Finally, we will translate knowledge to date and co-create an MDMA-assisted therapy protocol and roadmap for other entities to follow suit.

PROJECT RATIONALE

While the pandemic began as a physical health emergency, it has quickly evolved into a concurrent mental health emergency, referred to recently as the "Echo Pandemic" (CMHA 2020). Experts from around the globe believe that health care workers will likely face chronic anxiety, depression, substance use issues, acute stress and, eventually, PTSD (Mock, 2020). Given the exacerbation of COVID-19 related stress and trauma among a population already struggling with high rates of PTSD and TRD, it is imperative that we work to alleviate their suffering with the best evidence-informed tools we have.

This project will help address the current mental health crisis and prepare our systems for the COVID-19 post-pandemic future. We know that PTSD and TRD commonly co-occur (Campbell et al., 2007), that they are emerging at crises levels in HCPs, and are difficult to heal. Compounding these issues, current "gold-standard" treatments for PTSD suffer from non-response and dropout (Green, 2013; Najavits, 2015; Steenkamp, 2015) and those for TRD are often ineffective (Little, 2009; O'Leary et al., 2015). As a COVID-19 response, my team will refine our innovative and evidence-informed program to address and alleviate the mental health impacts on HCPs and other frontline responders.

There is strong community support for this research. We are working with Island Health (IH) and over 20 experts from across BC to modify the current expensive and inefficient ketamine treatment protocol used at IH; optimizing it with KAP-RTT. To date, our team has been supported by the regional health authority (IH), the Nursing Policy Secretariat, the Innovation Hub for the BC Ministry of Health, the Universities of British Columbia (UBC), Victoria (UVIC) and VIU, treatment Centres on mainland BC and Vancouver Island, the BC SUPPORT Unit Vancouver Island Centre, and most importantly, the participation and voices of HCPs with current diagnoses of PTSD and/or TRD. We are now synthesizing

knowledge and are poised to act quickly to operationalize our findings with our stakeholders who are either part of our team or supporting this initiative in other ways (see letters of support).

In August 2019, Dr. Dames was the recipient of a Patient-Oriented Research (POR) Team Assist Award from the BC Support Unit to conduct a Plant and Psychedelic Medicine Assisted Therapies (PMAT) Workshop on Visioning for Research, Policy and Practice which was held in October 2019, during which HCPs with lived experience of PTSD and TRD, as well as advocates, researchers, health professionals, policy and decision makers crafted recommendations. One participant highlighted her struggle with the toll that chronic workplace stress had on her first few years of practice: "My job requires me to witness incredible suffering. I watched a man take his last breaths in my final month of nursing school. School does not prepare us for this. We are busy and tired. It is easier and quicker to simply stuff it all down and move onto the next thing. And down it goes where it begins to fester."

Patient-Oriented Research (POR): A tenet of the POR is the inclusion of all relevant stakeholder groups (patient partners, researchers, Elders, health professionals, policy and decision makers) to plan and build our research program based on patient need. Having built POR capacity with stakeholders across BC, and building on the recommendations of HCPs with lived experience of PTSD and/or TRD (POR PMAT Visioning Workshop, October 2019), this research will enable our team to plan, co-design, evaluate and implement the novel KAP-RTT combination therapy protocol. This research provides a unique opportunity for us to learn from patient partners, HPCs experiencing TRD and/or PTSD, who fully understand the ineffectiveness of current treatment interventions and the need for novel approaches. Twelve patient partners are on the research team, some of which will participate in the first cohort to go through the program. They are join the program knowing that they are participating directly as a patient within a quality improvement framework, aiming to evolve and improve the program based on patient feedback. At least two patient partners will represent the patient voice in the steering committee co-led by IH and the BC Ministry of Health. In addition, we have 12 patient partners serving in an advisory capacity. With a commitment to cultural safety and humility throughout the development of the program, we have also included three Indigenous patient partners, and would welcome more Indigenous participants as the program grows. With funding from CIHR we will harness the momentum built, the expertise assembled, and extensive commitment of our team to develop the framework for the introduction of evidence-informed communities of practice with psychedelic-assisted therapies within the provincial healthcare system.

As research on the use of psychedelic substances for treating illnesses such PTSD and TRD experience a revival, so too does the re-emergence of a paradigm that underscores the importance of set (psychological expectations), setting (environment) and therapeutic relationships as critical elements for facilitating healing experiences and realizing positive outcomes (Tupper et al., 2015). With enormous local interest in addressing the current mental health crises, and based on the recommendations of the PMAT Visioning Workshop. This research will: 1) address the current lack of effective treatment options for those suffering from PTSD and TRD and 2) provide a promising targeted intervention to bring relief for HCPs. Flowing from this landmark event, as reported in the media, Dr. Dames won a *Canadian Institutes of Health Research Knowledge Synthesis Grant*, enabling the first step to translate knowledge from the PMAT event. We are now reviewing the rapidly growing literature, existing clinical trial data, and quality improvement processes to ensure we are adhering to best practice in the development of the KAP-RTT protocol.

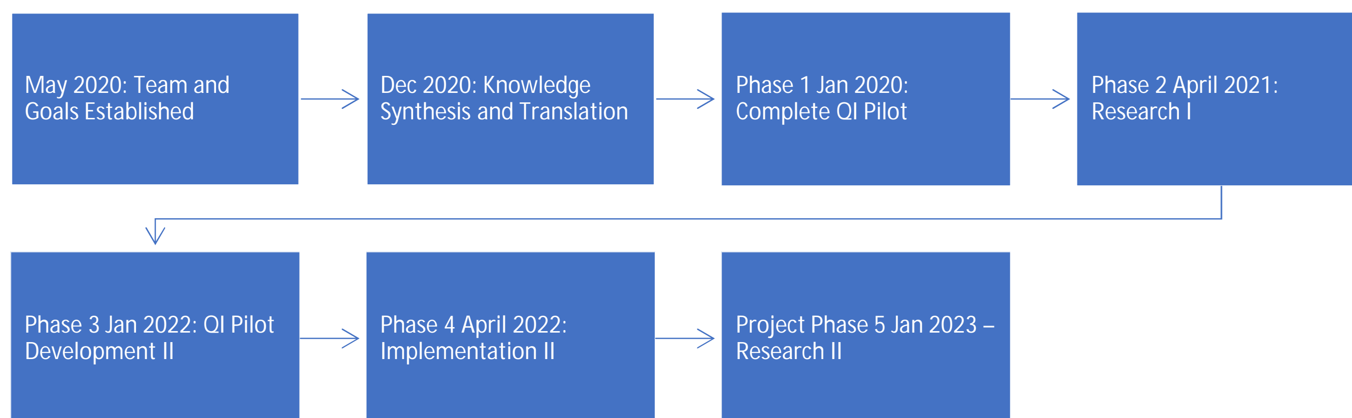
> ***Hypothesis:*** *KAP-RTT promotes connection to self, spirit and community and will significantly improve the mental health of HCPs suffering from PTSD and/or TRD. From this hypothesis, we will ask participants to respond to standard Health and Wellness Inventories before and after the program to identify significant impacts.*

Program Framework: The proposed research is in two stages. Stage 1 is the development stage where the KAP-RTT program is designed within the quality improvement framework and in partnership with the Ministry of Health, we focus on developing program efficiencies and impact. Stage 2 is the iteration

stage, where results are integrated into the program and the program improved, examined via a mixed methods study, and expanded to include other therapy adjucts (i.e. MDMA)

METHODOLOGY

Project Phases 1-4 Details. The below table provides an overview of the project phases.



October 2019-Sept 2020: In 2019, my team laid the groundwork for this program of research. With key milestones being: **1)** A landmark PMAT Workshop on Visioning for Research, Policy and Practice where I led a team that brought together multidisciplinary teams with an interest in psychedelic medicines. The collaborative relationships formed through this event and subsequent stakeholder thinktanks strengthened the shared KAP-RTT protocol goals and will continue to support and guide the process.**2)** A co-run Ministry of Health/Island Health steering committee comprised of key stakeholders and knowledge keepers**. 3)** Clinicians on this team and other provincial experts and stakeholders created a KAP medical procedure and therapy guidelines. It is now in the approval process at Island Health, including the MHSI Quality Committee first (approved on June 24, 2020) and now the Therapeutic Stewardship and Safety Quality Committee (interim approval scheduled). **4)** We are now approved and registered as a formal Quality Improvement Project within Island Health, which enables us to implement and test the combined KAP-RTT therapy guidelines, providing evidence-informed operational standards for KAP therapists and clinicians. **5)** With the support of a CIHR Knowledge Synthesis grant, we are funded to run a cohort through the quality improvement framework in the fall of 2020. We are examining the operational and fiscal structure, the KAP-RTT therapy guidelines, and the quality improvement measures, all of which enable us to understand the facilitators and barriers to develop and run a medicine-assisted psychotherapy program.

OUTCOMES:

1. Run the KAP-RTT program in partnership with IH (at a non-hospital IH facility) and as funds allow, iterate implementation of cohorts within an ongoing quality improvement process,
2. Submit Article for Peer Review –facilitators and barriers in KAP program development,
3. Ethics approval from Harmonized REB for research study.

Project Phase 1 Details – Jan 2021-April 2021: Quality Improvement Pilot I.

1) **Pilot:** This pilot will combine KAP and RTT, both of which will run concurrently (KAP-RTT) for 12 weeks. Participants will meet weekly in CoPs led by facilitators who will: encourage positive relationship building; teach practice integration; encourage honesty and positivity; facilitate honest self-expression. This cohort will receive 3 KAP sessions together (weeks 4, 5, and 7) followed by ongoing weekly integration sessions and group debriefs. Finally, there will be a wrap-up where participants will be invited to engage with RTT alumni CoPs and, a formal referral back to the referring care provider will

take place. Concurrently, we have already been meeting with the Island Health Ethics Board to prepare them for our application. By late 2020, will submit an ethics application to implement the full program of research to the Harmonized Ethics Board which oversees approvals for IH and the project's academic partners.
2) Develop a process framework, noting facilitators and barriers, mapping the patient experience, and the cost to treat compared vs not treating.
3) Refinement of Knowledge Mobilization Plan: With patient partners, we will develop and publish medically and culturally safe therapy guidelines and the QI evaluation report on our program's website to mobilize knowledge related to the operational feasibility of a combined KAP-RTT program. This could provide a roadmap of sorts for other public entities to take up this innovative treatment option.
4) Continue synthesizing knowledge on the literature review of MDMA-assisted Psychotherapy (soon available as a therapy adjunct). This work will support the project by enabling additional grant applications.
PHASE 1 OUTCOMES:

1. Run the KAP-RTT program in partnership with IH (at a non-hospital IH facility) and as funds allow, iterate implementation of cohorts within an ongoing QI process,
2. Submit article for peer review –facilitators and barriers in KAP program development.
3. Ethics approval from Harmonized REB for research study.

Project Phase 2 Details - April 2021-Dec 2021: Research I. Once the KAP-RTT prototype is established, we will use a mixed methods waitlist control design to explore the impacts on those receiving KAP-RTT compared to a control group, and those who receive RTT only. We plan to run 6 randomly assigned groups of 12 to accommodate the waitlist control design, with 2 groups as controls, 2 getting RTT only, and 2 getting KAP and RTT. Before the start of KAP-RTT and upon completion. We will collect:

- GAD-7 (Generalized Anxiety Disorder) to measure anxiety,
- Patient Health Questionnaire-9 (PHQ-9) to measure depressive symptoms,
- PCL-5 as a PTSD measure
- Sheehan Disability Scale (SDS) to rate global functioning
- Adverse Childhood Event Score (ACEs) to establish a measure of developmental trauma
- Self-Compassion Scale to explore changes in self-concept and self-acceptance
- Mystical Experience Questionnaire (MEQ30) to explore the experiential processes engaged during the KAP sessions
- Heart rate variability as a measure of baseline stress tolerance and polyvagal theory.
- Variables that typically predict health and wellness such as age, sex, SES, marital/relationship status, addiction tendencies, marital/partner relations, parenting issues, financial stress, social support, chronic health issues

Data gathered before and after the 12-week treatment period will measure intervention impacts between each group. At three months, we will review data from each group.

Qualitative experiences will be captured through focus groups (for RTT and RTT+KAP groups) at the end of the pilot. Focus groups will follow Merriam's basic qualitative approach (Merriam, 2014), which includes a semi-structured interview followed by a back and forth analysis to identify themes. We will validate results through a member checking process and triangulate results with the literature. Follow-up interviews with participants at the 3, 6, 12, and 24 month mark will explore long-term effectiveness. Those in the control group will then be offered the option to participate in RTT or RTT+KAP. While we are learning from this QI pilot and program of research, we will also be working to evolve and expand to include RTT + MDMA-assisted psychotherapy.
PHASE 2 OUTCOMES:

1. Quantitative and qualitative data on the effectiveness of the KAP-RTT protocol
2. A manuscript submitted for peer-review – describing study results

3. Publication and conference dissemination of knowledge gained re. the development of an MDMA medical and therapy protocol
4. Use learnings from KAP-RTT study to inform the MDMA protocol development process.

Project Phase 3 Details - Jan 2022-March 2022 Pilot Development II: Combining MDMA with the RTT Community of Practice model and using data collected in the previous study, we will expand the program of research to include MDMA within a Quality Improvement program.
PHASE 3 OUTCOMES: Complete a literature review of MDMA-assisted therapy.

Project Phase 4 Details – April 2022-Oct 2022 Quality Improvement Pilot II: We will run the expanded program (MDMA-RTT) within the quality improvement framework, aiming to pair resilience development with other psychedelic assisted healing modalities. With ethics approval from Harmonized REB. Participant follow-up will continue, with participant responses informing program improvements and academic paper development.
PHASE 4 OUTCOMES:

1. A quality improved combination protocol,
2. REB approval
3. KT through internal newsletters at VIU and IH and a jointly created media release.

Project Phase 5 Details – Jan 2023-Dec 2023 – Research II. The research design of Phase 5 will develop from knowledge gained in phases 1-4, and will both build upon and respond to findings. I will continue applying for funding for an ongoing program of research in partnership with academic institutions.
PHASE 5 OUTCOMES:

1. Submit a manuscript for peer-reviewed publication.
2. Complete report on the past and planned KT and mobilization efforts.
3. Development of Research II research design.

KNOWLEDGE TRANSLATION, OUTCOMES, AND IMPACT

Investing in HCP resilience and mental health improves healthcare and patient outcomes by improving staff retention, reducing sick days and medical errors, and promoting quality patient care. This further reduces patient morbidity and mortality. Because status quo treatment options have underserved or failed most with PTSD and TRD, this work, informed by healthcare provider (as experts and patients), will pave the way and promote access to other promising and research-informed psychedelic-assisted therapies as they soon become legal for medical use. This is an iterative process, encouraging and interweaving patient-partner feedback as the protocol is developed. We are translating and mobilizing knowledge by:

- Collaboratively working on consensus on an evidence-based KAP-RTT combination therapy protocol to be used at IH and across BC;
- Co-creating a medical procedure and therapeutic guidelines that will inform implementation of other psychedelic-assisted therapy work in Island Health and other agencies across BC and Canada.
- Co-developing a roadmap that details the facilitators and barriers that emerged as we developed the first resiliency-supported psychedelic assisted therapy program in BC. To narrow the gap between research and implementation, we will share our learnings formally and informally, providing insights to other health authorities in BC and beyond;
- Collaborating on funding opportunities for additional research projects with resiliency development as the primary evidence-informed treatment strategy – supported by psychedelic-assisted psychotherapies and other healing modalities to address treatment resistant MH conditions.
- Accelerating and integrating the use of pre-clinical research into a learning health system through close collaboration of IH clinicians and POR stakeholders from across BC;
- Continuing to directly translate knowledge by educating providers and leaders, which informs healthcare policies and practices that alleviate workplace induced mental distress.
- Rapidly translating real-time evidence for transforming research into clinical guidelines and practice to immediately respond to the mental health consequences of the COVID-19 pandemic.
- Rapidly mobilizing knowledge to an international audience to promote the adoption of promising and innovative mental health therapies (through publication and stakeholder events) that address treatment resistant mental health conditions.

Dr. Wei Yi Song, Head of Psychiatry at Island Health and a core member of this project's clinical team notes high levels of unmet need for those managing complex mental conditions such as TRD and PTSD. "Backed by the research evidence and trials the project team is conducting, psychedelic-assisted therapy presents an exciting new treatment modality," says Song. "I have been practicing psychiatry for more than 20 years and I am always looking for innovative ways to bring healing to our patients." Our multidisciplinary and multi-agency team is narrowing the gap between health research and implementation by breaking down provincial silos between researchers, policy makers and the clinicians on the frontline of healthcare delivery. We are doing this by engaging patients, which in this case are HCPs with experience with PTSD or TRD, throughout the program planning, development, research, and knowledge mobilization phases of this project.

FEASIBILITY, TIMELINE, SUPPORTS, FUNDING

COVID-19 Social Distancing Guidelines: This project is able to comply with all COVID public health recommendations. The resilience course is now available for virtual delivery and all planning and meeting activities are done virtually.

Stakeholder and Structural Supports: Dr. Dames has been working with the Island Health (IH) ethical review board, policy-makers, and IH, VIU, UBC, UVIC research experts for the past year to vet this important work. Her talents are well suited as an experienced project leader and resilience expert, which lies at the centre of this community-based mental health strategy. Furthermore, she is a co-developer of

the well-established Psychedelic Psychotherapy Forum, a well-established conference, which draws an international crowd. In addition, she recently accepted the co-chair role for the Island health Psychedelic Assisted Therapy Steering Committee, working alongside local experts in the field of psychedelic assisted therapies. In addition to Island Health support, the project is supported and celebrated by experienced mixed methods researchers at UBC, UVIC, and VIU. She is also working closely with government and private agencies who have experience with this treatment and are highly motivated to collaborate on further research. Given the support for this project and with Dr. Dames as the lead, the project is highly feasible. **Timeline.** As illustrated in Appendix A, the timeline to plan, develop, and implement is already in process and is generous, making room for any number of kinks that are likely to occur as the team trail blazes in this emerging area. Dr. Dames is working with the Island Health Policy Department and Ethics Boards to ensure her timelines are generally accurate and realistic. **Funding:** While Dr. Dames secured funding to complete the KAP-RTT QI process, her time remains unfunded and is the costliest part of this project (with no time allocated for research in her FT position). With this funding, Dr. Dames will have the time (outside of her full time teaching workload) to move this project forward. We are now working on a funding structure for sustainable public access through government agency collaborations, private contributions, sponsorships, donations, and grants.

MY TEAM & I

My team is multi-agency and multi-disciplinary with a solid track record in policy making, research, clinical expertise, program development, and service delivery. Each collaborator adds expertise and resources to ensure the team meets its objectives. We are ready to mobilize the necessary resources to complete this project within the required timeframe.

In terms of my rationale as the leader of this project: As an early career researcher, I will use my knowledge and relationships provided by this role to support and leverage the resources required to actualize my research findings in the field. As a nurse educator, I work directly with students in the clinical setting, providing a unique mentorship opportunity, bridging theory with practice. I am well networked as an active member of the research team for KAP BC and a co-developer of the Psychedelic Psychotherapy Forum, which gathers international experts in the area of therapy and psychedelic medicine. Because I still practice as a nurse on the frontline, I can view this program of research through the lens of those who grapple with high stimulus and stress. As a researcher and a person with lived experience of burnout and PTSD, I see the research process as an intervention in itself, engaging participants in a community that feels safe to re-connect (to self, to spirit, to others), to assess their vulnerabilities, and learn tools that bolster resilience, address trauma and enable healing.

Name	Affiliation	Expertise	Role
Dr. S. Dames	VIU, Nursing	Developed RTT, teaches RTT to HCPs, Emerging leader in psychedelic therapy	Project Lead: Responsible for grant outcomes and reporting. RTT lead.
Dr. W. Song	IH, Director of Psychiatry	MD, PTSD and TRD treatments, anesthesiology, ketamine infusions	IH Admin Project Oversight
Dr. C. Watler	IH, Psychiatrist	PTSD and TRD, thought leader	Advocate for better treatments
G. Peekeekoot	RN	First Nations, medicine adjuncts	Lead RN for KAP treatment
W. Taylor	Consultant	KAP therapist	QI measures and data
M. Grant	Consultant	Anti-racism, BiPoC	Equity & Diversity Training
Dr. L. McCunn	Assoc Prof, VIU	Environmental Psychology	Overseeing the 'setting'
T. Haspect	Island Health	Principles & Ethics, Educator	Guideline Development
Dr. Z. Walsh	Assoc Prof, UBC	PTSD & therapy adjuncts	Design and REB applications
Dr. O. Krigolson	Assoc Prof, UVic	Lead in the Neuroeconomics Lab at UVic	Lead for quantitative data analysis
Dr. G. Prinsloo	Cedars Treatment	MD, mental health and addictions	KAP Site administrator
Dr. P. Kryskow	MD Private Prac.	KAP expert and trainer.	Oversight of KAP-RTT protocol
M. Roper	Island Health	Spirituality, Addictions, Therapy	Cultural safety (sex,gender,race,etc.)
Dr. K. Tupper	UBC and Private	Psychedelic Therapies and research	MDMA protocol expert/consultant
G. Manson	VIU	Elder in Residence	Access and reconciliation efforts
12 patient partners	IH, VIU, UVIC, FNHA,private, etc.	HCPs that meet the treatment criteria. Some remain anonymous	Help with all stages from synthesis to implementation
Dr. Hasselback	Island Health	Chief Public Health Officer for IH	Harm Reduction Efforts
R. Moyer	PhD student, UBC	Psychology Major, Indigenous focus	Assist with REB applications
G. Russell	Island health	CI Harm reduction coordinator	Harm reduction, TiP
Students (4)	VIU, Island Health	BsN Nursing Students, MD Resident	POR training & literature review

These are unprecedented circumstances. In addition to an ongoing international mental health crises, this pandemic is the most serious international crisis of our generation. HCPs are serving at the frontline of this fight, which is taking a serious psychological toll. Our team is eager to use innovative and evidence-informed approaches to support them in their time of need. Furthermore, our work is strategically placed to enable patient partners (our very own HCPs) to not only guide the research in this COVID-19 response effort, but they are also the ideal population to lay the groundwork for an exciting new wave of psychedelic interventional health research to come. In this manner, their voices will be heard and the resulting framework for treatment delivery will reflect the knowledge users and patient partners' needs as BC examines and moves forward with a revolutionary mental health strategy that integrates RTT communities of practice with psychedelic-assisted therapies.

KAP-RTT: Workflow/Budget allotment
CIHR – MAY Knowledge Synthesis Grant / Philanthropist/RIF/VIU

Roper	289 hours x $50 per hour - Leading the cultural safety components of the project - infusing into both the therapeutic guidelines and the quality improvement planning process. She is overseeing the IH/MOH steering committee development and is already engaged as a core member and collaborator of the Island Health team, sitting as KAP therapist for 3 sessions. HIRED $14,079 (inc. frings).
P.Dames	Organizational structure, website creation, develop billing mechanism, online screening forms, business planning, define operational quality improvement measures, all intake screenings, with Kate Wilton, co- lead roots implementation ($2500 - 62.50 hours @$40/hour). 250 hours @40/hour. 20 screening sessions at $50/each ($1000). HIRED $15,083 (inc. fringe)
Taylor	Quality improvement measures 125 hours @ $40/hour. Define pre and post measures, patient experience mapping, sitting as KAP therapist for 3 sessions. [working around fnha job] CONTRACTED $5,000
Kryskow	48 hours at $250/hour. Overseeing the KAP project, train the trainer, MD expert. CONTRACTED $12,000
H and C Watler	37 hours at $250/hour. Developing and implementing the client intake process. CONTRACTED $7800 (REST TO BE BILLED TO MSP)
Peekeekoot	36 hours at $75/hour. Overseeing medical/safety requirements, KAP clinician (3 sessions), and RN role description. CONTRACTED ($2,675)
Wilton	12 weeks + planning co- lead roots implementation ($2500 - 62.50 hours @$40/hour). [working around LaFF job] HIRED ($2,640)
Expert Honorariums $500	Dohl, Lemp, H Watler
Student(s)	Moyer – PhD $500, Resident - Good $500, Bartle (70 hour work op)
Geraldine Manson	$40/hour = 24hours for 12 Roots Groups, 24 hours for KAP sessions = $1,920 10 meetings at 1.5hours each = 15 hours = $600. FLAT RATE total = $2520

Knowledge Synthesis and Translation Activities
Ketamine-assisted Psychotherapy and Communities of Practice: Building the Foundation with Knowledge Synthesis and Translation Activities

Goals:

- **Literature Synthesis via reviews:** community-based treatment models (working with Polyvagal Theory), ongoing ketamine and KAP literature reviews, provincial scoping review of current KAP practices.
- **Intake Protocol development:** reviewing literature on best-practice medical screening and intake processes. Identifying priority participant measures pre and post program.
- **Quality Improvement process:** Develop an evaluation mechanism to identify program costs, capacity needs, education, and space needs.
- **Develop Medical and Therapy Guidelines:** Complete approval process for the KAP medical procedure and develop psychedelic-assisted therapy guidelines, which will provide a detailed road map of the necessary ingredients of a culturally and psychologically safe program offering.
- **Develop an Education Plan:** Work with provincial stakeholders to develop an education plan for providers to safely and effectively delivery medicine-assisted therapy.
- **Report on Facilitators and Barriers:** With this being the first publicly offered psychedelic-assisted therapy program, we do and will have much to share about the process. We will provide a roadmap of tasks and learnings from development through program implementation.

Task Assignment - Lead(s) bolded:

1) **Bartyl and S.Dames:** Literature Synthesis of the community-based mental health treatment model (Figure 1): May – June: Robyn Bartle (research assistant) will complete a robust literature review focussed on methods to measure polyvagal theory and other legal assisted therapy options. Submit article for publication: summarizing the research on KAP (or other assisted therapies) and resilience and connection focussed communities of practice and how these efforts interweave.
    a) Ketamine research – A thorough review, with knowledge translation in the KAP medical procedure.
    b) KAP research – Provincial scoping review: Erika McLaren BSW, MSW, RSW
    c) Group therapy versus individual therapy- impact differences (polyvagal theory? Privacy concerns)?
    d) Other topics: Communities of Practice – other research (not included above)? EMDR - research? CBT - research? EFT- research? Cannabis-assisted Psychotherapy – research – clinical trials?
    e) MDMA as therapeutic adjunct.
2) Develop the Intake Protocol and evaluate all healthcare provider for the first participant cohort –**Crosbie Watler,** Andrea Lemp, Helen Watler
3) Develop and refine the Therapy Guidelines for QIP testing – **Roper**, Kryskow, Taylor, Peekeekoot, Loshny, Manson, Demers.
4) Develop the Quality Improvement Plan/Pilot Evaluation and Fiscal sustainability mechanisms. Because the initial pilot is being run through a quality improvement program at Island Health, we need a formal organizational structure that can fund, staff, and sustain this work – enabling articulate operational and systemic facilitators and barriers of running a combined KAP-RTT

program. This work also involves working with organizations to establish a common structure including software set up, legal requirements, etc. **P.Dames, S. Dames,** Taylor, Moyer

  a. Fee for service contracts and software needs for collecting and maintaining client data with Island Health. **P.Dames**
  b. Integrating pre and post treatment series packages with guideline development, helping to map and budget for the ideal client experience - **Taylor**
  c. Ensure treatment environment is resourced and medically and therapeutically sound – **Peekeekoot**

5) Refinement of Knowledge Mobilization Plan: Both the development (and publication) of medically/culturally safe therapy guidelines and a QI/evaluation plan to better understand the operational feasibility of a combined KAP-RTT program and will provide a roadmap for other public entities who take up this innovative treatment option and will also support the project by enabling large-scale collaborations across BC and additional grant applications. **S.Dames**

6) Development of an Education Plan: We will be bringing in trainers to work with clinicians and therapist, ensuring we are using best practice techniques and maximizing the impact of therapeutic relationships and environment – **Kryskow, S.Dames,** Roper, Peekeekoot, Manson

FIGURE 1: The Community-Based Treatment Model

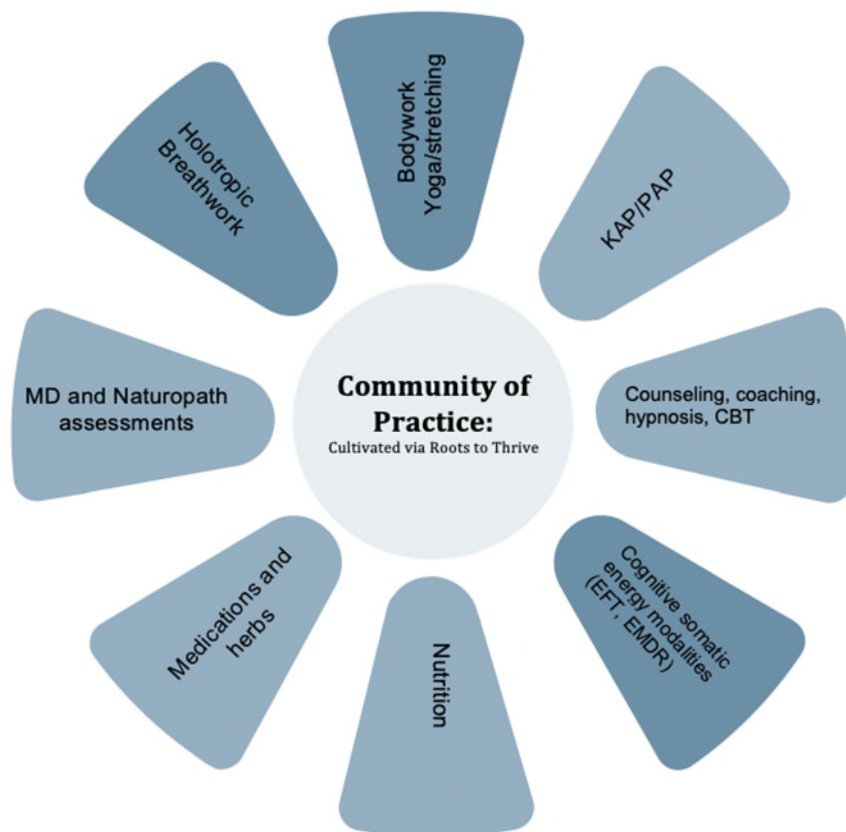
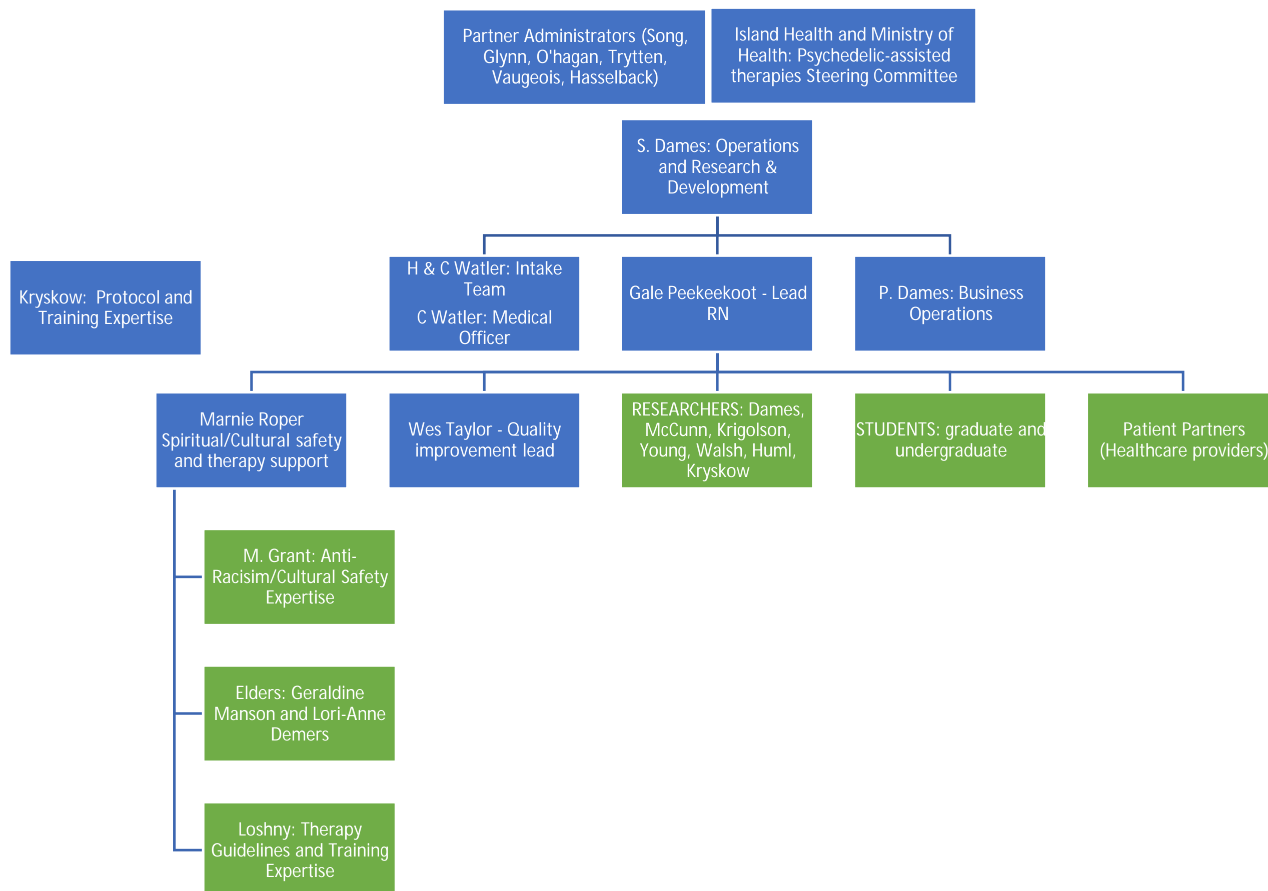


Figure 1: Community-based Mental Health Strategy

Figure one provides an illustration of our community-based outpatient mental health strategy, which evolved from the Roots Theory and is mobilized through the Roots to Thrive (RTT) program. We are operationalizing this community-based mental health model with the RTT communities of practice, which promote awareness, regulation, heartful connection and alignment. To remove barriers to healing and ultimately connection, we integrate these practices more deeply by combined with ketamine-assisted psychotherapy (KAP). Led by a patient-oriented program development and research team, we will develop, operationalize, and study the RTT community of practice with KAP. Then, we will expand to a more inclusive treatment model, including other holistic and medicine-assisted therapies as they become available in Canada.

KAP-RTT Milestone Roadmap
Roots to Thrive Development and Research (MSFHR Grant) 2017-2020
Psychedelic Medicine Assisted Therapies (PMAT) Visioning Event (BC Support Unit Grant)- Oct 2019
Project approved as a formal Island Health Quality Improvement Project - May 2020
Ongoing knowledge synthesis process to inform program and research planning.
Development and Submission of KAP Medical Procedure for Island Health approval (Regional Initiatives Grant) - May 2020
DECISION MAKER STRATEGY SESSION: co-charied with the Canadian Psychedelic Association - Provincial policy makers and entheogen agency leads (June 2020)
Media Release - Announcing project publicly
Create interagency MOU (done). Have Signed (in process).
Define medicine constitution and procurement process (now working with IH pharmacy team)
Hold first Steering Committee (Island Health & Ministry of Health co-sponsoring) to oversee this and other psychedelic-assisted therapy projects - In Process (Sept 2020)
Complete Quality Improvement Evaluation Measures- In process
Complete first draft of Therapy Guidelines - In process
Establish a sustainable collaborative structure to ensure ongoing funding for a public access to this combined KAP-RTT therapy program - In Process (by Oct 2020)
Have Affiliations Signed (by Oct 2020)
Meet with VIU/Island Health and Workers Comp Insurance Providers - shared expense model for those on long-term disability related to burnout, TRD, PTSD
Recruit the first cohort of 10-12 participants to go through quality improvment process (Tentative: July-August 2020)
Run first cohort through the newly developed RTT-KAP program (Tentative: Sept-Nov 2020)
Adapt and evolve program to improve effectiveness and efficiencies (January 2021)
With forecast of MDMA being legalized for PTSD in August 2020 - Begin MDMA medical and therapy protocol with Island Health.
Gain Research Approval from REB's (Apr 2021)
Run a mixed methods observational study, once program is established (Feb 2022)
Running parallel - project with Royal Roads University - studying the effect of RTT groups on early onset dementia (Date TBD)
Complete a knowledge synthesis process to inform expanded program and research planning.
Adapt and expand program to include other medicine-assisted modalities combined with RTT (Aug 2021)
Run a revised mixed methods observational study on the adapted program (Nov 2022)
Continue adapting and evaluating within an ongoing quality improvement process. Develop an overarching program of research to support and direct programming efforts (2020-2023)
While knowledge mobilization will happen throughout the project, now we focus all efforts on publication and other formal and informal channels to mobalize our learnings (2019-2023)
Planning and Development: Completed
Knowledge synthesis & QI Prototype: In progress
Ongoing KT & Research: To be completed

Communication and Leadership Structure



Development Consultants

Joining as Core Team (ongoing involvement)

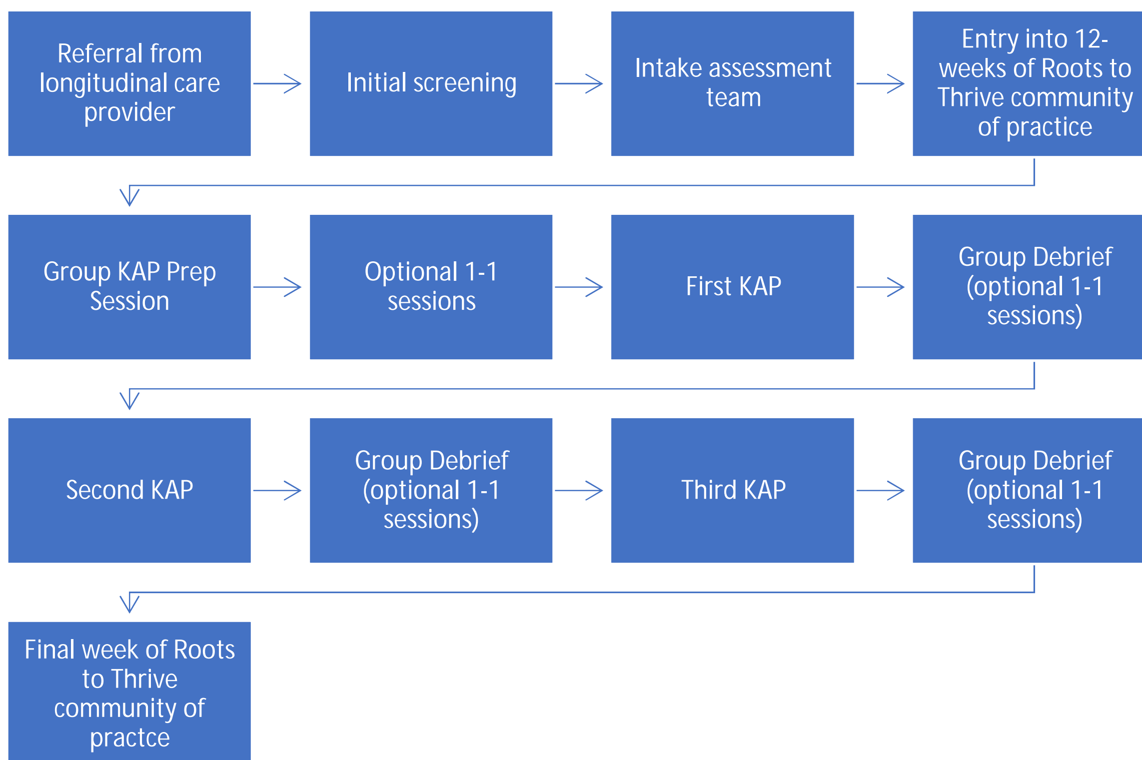
Collaborating Agencies and Stakeholder Partners

Island Health - Research and facility support: Drs. Trytten & Waterhouse
Vancouver Island University – Research and facility support: Drs. Mulligan & Vaugeois
University of Victoria – Research support (Neuroscience Lab): Dr. Krigolson
University of BC – Research support: Dr. Walsh
Numinus – Medical Procedure Development: Wallin & Fong
Cedars – Potential Future Collaboration – residential site: Dr. Prinsloo
MAPS Canada – In Discussion
The Ministry of Health – Innovation Hub
BC SUPPORT Unit Vancouver Island Centre: Dr. Sbotofrankenstein

Mapping the Patient Experience of KAP within a Roots to Thrive (RTT) Community of Practice

Core Documents: Referral Form, Medical Procedure: Non-IV Ketamine for the Treatment of Mood Disorders, KAP Therapeutic Guidelines

KAP-RTT Milestones over 12-weeks



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