

THE CANADIAN COLLABORATIVE FOR CHILDHOOD CANNABINOID THERAPEUTICS

ANNUAL S REPORT S

Prepared by: Zina Zaslawski Jessica Steer

MESSAGE FROM DR. LAUREN KELLY



It has certainly been a very exciting year, and I am pleased to provide you with this report as an update on the latest developments within C4T.

C4T continues to pursue its mission of conducting and disseminating high-quality research on the safety and efficacy of medical cannabis in children. Our work is informed by patients, parents, healthcare practitioners, policy makers, and the wider scientific community.

We currently have 112 dedicated members, and this year we have seen remarkable participation, with almost 30 members attending each of our monthly meetings. THANK-YOU to our members who continue to grow the reach of our work. This level of engagement highlights our commitment to driving advancements in pediatric cannabinoid therapeutics.

A significant milestone in our journey was on June 24, 2023, when C4T hosted the first Pediatric Special Interest Group meeting at the International Cannabinoid Research Society (ICRS) conference. At this event, we brought together expert panelists from Australia, Canada, the United Kingdom, and the United States to engage in thoughtful discussions about pediatric cannabinoid therapeutics.

Looking ahead, we are gearing up to initiate three clinical trials and launch a national observational study. These undertakings will allow us to generate data that can guide medical practitioners, policymakers, and caregivers in making informed decisions regarding the use of cannabis for medical purposes in children.

Thank you for being part of this remarkable journey, and I look forward to our important work we will achieve in the future.

Lauren Kelly Scientific Director, C4T



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C4T GOALS



ADVANCING CLINICAL RESEARCH AND PATIENT CARE: To advance the field of pediatric cannabinoid therapeutics through rigorous clinical research and to ultimately improve patient care, safety and outcomes.



KNOWLEDGE DISSEMINATION AND AWARENESS: To disseminate valuable knowledge and raise awareness about the use of pediatric cannabinoid therapeutics within the scientific community, healthcare practitioners, policymakers, and the public.



BUILDING A ROBUST RESEARCH COMMUNITY: To create a strong, collaborative, and interdisciplinary research community committed to improving the understanding of pediatric cannabinoid therapeutics.

TRIAL UPDATES

CAN-CHA: A Multi-Centre, Tolerability Study of a Cannabidiolenriched Cannabis Herbal Extract for Chronic Headaches in Adolescents: the CAN-CHA trial

The CAN-CHA trial will examine the safety of a CBD-enriched herbal extract oil to see what effect it has on adolescents and their headaches.

- Recruitment has started, with one site launching in late 2023.
- Our goal is to enroll 20 adolescents between the ages of 14-17 at 3 sites: BC Children's Hospital, the Neurology Centre of Toronto and IWK Health Centre.
- This study is funded by SickKids and has been registered with <u>ClinicalTrials.gov</u> under NCT05337033.

CAN-PONC: A Randomized, Double-Blind Tolerability Trial of Cannabinoids for Symptom Management in Children with Cancer

The CAN-PONC study aims to describe the tolerability of escalating doses of two CBDenriched cannabinoids treatments and one balanced cannabinoids treatment in children with cancer.

- We have received a No Objection Letter from Health Canada
- We received ethics approval from the University of Manitoba and are in the process of getting ethics approval at study sites
- This study is funded by the Canadian Institutes of Health Research (CIHR) and the Canadian Cancer Society (CCS) and has been registered with <u>ClinicalTrials.gov</u> under NCT05754840.
- This study will be done in two parts and include a total of 90 children ages 4-17 who have received a cancer diagnosis.

CAN-DRE: A Triple-Blind, Placebo-Controlled, Randomized Clinical Trial of Cannabinoids for Drug Resistant Epilepsy (CAN-DRE) in Adults and Children

The CAN-DRE study will investigate CBD alone and in combination with THC compared with placebo in adults and children with drug resistant epilepsy.

- We have received funding from the Canadian Institutes for Health Research (CIHR) in the Project Grant competition.
- Presubmission meeting was held with Health Canada to discuss appropriate regulatory approach
- The protocol is currently in development to be submitted early 2024.
- This trial will recruit 90 children and adults with drug resistant epilepsy across 8 sites in 4 provinces.

CAN-RWE: Real World Evidence on the Use of Medical Cannabis in Pediatric Patients: A Prospective Observational Study

The CAN-RWE trial aims to explore how different cannabis products help children with different types of symptoms and to better understand the long-term harm:benefit profile of cannabis used for medical purposes in children.

- Recruitment has begun, with the aim of enrolling 500 Canadian children between the ages of 3-17 who use medical cannabis.
- This study is funded by the Canadian Institutes of Health Research (CIHR) and the Canadian Cancer Society (CCS) and has been registered with <u>ClinicalTrials.gov</u> under NCT05863910.
- This study includes any child aged 3-18 years with an authorization for medical cannabis and has additions subgroups for children with cancer and children with epilepsy.

SELECT PUBLICATIONS

We are proud to share our recent publications from the past year. Below you will find our publications and abstracts, each offering valuable insights into medical cannabis for children. Please click on the titles to access the full publication

<u>Medical cannabis for children: Evidence and</u> <u>recommendations</u>. Canadian Pediatric Society, 19 October 2023

Interest in using cannabis products for a medical purpose in children under the age of 18 years is increasing. There are many medical cannabis products available that can include cannabidiol (CBD) or delta-9-tetrahydrocannabinol (THC), or both cannabinoids. This statement reviews the current evidence and provides recommendations for using medical cannabis in children. CBD-enriched cannabis extracts containing small amounts of THC have been evaluated in a small number of paediatric patients, and further research is needed to inform clinical practice guidelines. Given the widespread use of medical cannabis in Canada, paediatricians should be prepared to engage in open, ongoing discussions with families about its potential benefits and risks, and develop individualized plans that monitor efficacy, reduce harms, and mitigate drug-drug interactions.

DISSEMINATION AND AWARENESS KNOWLEDGE

<u>Cannabinoids for symptom management in</u> <u>children with cancer: A systematic review and</u> <u>meta-analysis.</u> Cancer, 28 August 2023

This study looked at how cannabis products are used in children with cancer. They wanted to find out if these products are safe and effective for kids with cancer. They searched databases and found 19 different studies with a total of 1927 children with cancer. These studies used various forms of cannabis to help with symptoms, especially nausea and vomiting caused by chemotherapy. In some studies, children experienced side effects like sleepiness, dizziness, and dry mouth from using cannabis, but there were no serious problems reported. However, the researchers say research is needed to better understand the right dosages, safety, and how well cannabis works for children with cancer because more and more people are interested in using it for medical purposes.

ISSEMINATION AND KNOWLEDGE AWARENESS

<u>Co-designing clinical trials alongside youth with</u> <u>chronic pain.</u> Paediatrics & Neonatal Pain, 8 May 2023

This study explored how to involve young people in medical research to make sure it's done in a way that's beneficial for them. We talked to 16 young people between the ages of 15 and 18 in Canada. We had discussions about how to get young people interested in research, what might stop them from participating, and how to design research projects that work well for them. The youth said they'd rather be invited to join a study by their doctor instead of on social media. They also mentioned that it's important to build a good relationship with the research team. One thing they found challenging was the time it takes to be part of a study. They also gave feedback on how to design the research and how to collect information.

This study shows that listening to different young people helps make medical studies with children better. It also gives a guide for other researchers on how to involve young people in research using online discussions.

KNOWLEDGE DISSEMINATION AND AWARENESS

<u>Medical cannabis in schools: The experiences of</u> <u>caregivers.</u> Paediatrics & Child Health, 4 May 2023

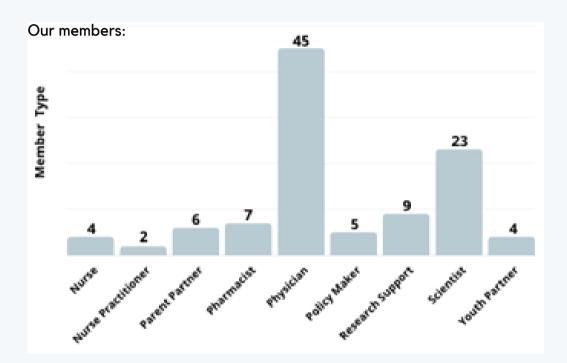
This study wanted to find out how caregivers of school-aged children in Canada who use medical cannabis cope with the challenges of giving it to their kids. We talked to 12 caregivers whose children had conditions like drug-resistant epilepsy or autism. About half of these kids used medical cannabis during school, and most caregivers felt it was a good or okay experience, but they didn't have enough information about it.

The study identified three main categories of challenges: dealing with the stigma of using medical cannabis, finding someone to authorize it, the cost, dosing, and supply issues. Caregivers also had to become advocates for their children, which required a lot of knowledge, skills, and finding good sources of information. Despite these challenges, caregivers were determined to make it work and saw positive outcomes. KNOWLEDGE DISSEMINATION AND AWARENESS Removing barriers to accessing medical cannabis for paediatric patients. Paediatrics & Child Health, 31 March 2023

Medical cannabis may offer therapeutic benefits for children with complex neurological conditions and chronic diseases. In Canada, parents, and caregivers frequently report encountering barriers when accessing medical cannabis for their children. These include negative preconceived notions about risks and benefits, challenges connecting with a knowledgeable healthcare provider, the high cost of medical cannabis products, and navigating medical cannabis product shortages. In this manuscript, we explore several of these barriers and provide recommendations to decision-makers to enable a family-centered and evidence-based approach to medical cannabis medicine and research for children.

MONTHLY MEETINGS

Between 18-24 members attended each monthly meeting this year. We have had the pleasure of hearing from many different presenters.



January 2023 - Dr. Lynda Balneaves & Dr. Cody Watling: "Cannabis vaping among youth and young adults in Manitoba - The CaVED Project"

February 2023 - Frank Chen: "Preliminary data & analyses of Medical Cannabis for Neurologic Disorders: a Retrospective Chart Review"

BUILDING A ROBUST RESEARCH COMMUNITY

April 2023 - Dr. Jennifer Anderson: "Evaluating a Collaborative Care Model for Children using Cannabis for Medical Purposes"

May 2023 - Dr. Karolina Urban: "Patient transition from Medical Cannabis by Shoppers and overview of MyMedi.ca (Avicanna Medical Platform)"

September 2023 - Dr. Rebecca Haines-Saah: "Youth and Cannabis - Myths, Fears, and Facts learned from TRACE"

October 2023 - Dr. Robert Laprairie: "Rodent model pharmacology and safety considerations for plant cannabinoids and metabolites"

November 2023 - Safia Hassan, Marko Cavar and Maria Aoun from Health Canada: "Adverse Reactions with Cannabis Products in Canada"

December 2023 - Dr. Kim Hellemans: "Predicting problematic cannabis use among a young adult population"

PEDIATRIC SPECIAL INTEREST GROUP MEETING

On June 24, 2023, C4T held a pediatric special interest group meeting at ICRS. We brought together expert panelists from Australia, Canada, the United Kingdom, and the United States to discuss pediatric cannabinoid therapeutics.





Key Highlights:

- Dr. Elizabeth Thiele was our keynote speaker and gave a great talk: "The Role of Cannabinoids in the Treatment of Epilepsy: More than Millennia in the Making"
- Our expert panelists included Alison Bowers, RN, PhD; Myfanwy Greham, BPharm; Matt Hughes; Bruce Crooks, MD; Trinity Lowthian; and Elizabeth Thiele, MD. They provided valuable perspectives and engaged in thoughtful dialogues during our round table discussion.





For those who were unable to attend or want to revisit the discussion, you can watch the meeting recording at <u>ICRS Pediatrics Special Interest Group</u> <u>Meeting (June 24, 2023) - YouTube</u>

CONTACT US

Email: <u>C4T.Canada@gmail.com</u> Phone Number: (204) 891-0032 Mailing List: Sign up here - <u>C4T Newsletter List</u>

WANT TO JOIN C4T?

Open to doctors, nurses, pharmacists, social workers, scientists, youth, and parents. Email <u>C4T.Canada@gmail.com</u> to learn more about these opportunities.





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