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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Real World Evidence on the Use of Medical Cannabis in Pediatrics: A Prospective Observational Study (CAN-RWE)

Principal Investigator: Dr. Lauren Kelly

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You are being asked to take part in a real world evidence research study that will track your child's response to medical cannabis over time. This includes how medical cannabis may affect their pain, sleep, mood, behaviour, and the overall quality of life for your family over a two-year period. Before agreeing to participate, it is important that you read and understand the following explanation of the proposed study.

The following information describes the purpose, procedures, benefits, risks and precautions associated with the clinical work and the research. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this study, you should understand enough about its risks and benefits to be able to make an informed decision.

This is known as the informed consent process. Please ask the study coordinator to explain any words you do not understand before signing this consent form, you can call them anytime to ask questions at 204-891-0032 or 833-532-1440 (toll-free) or send them an email: C4T.Canada@gmail.com. Make sure all your questions have been answered to your satisfaction before signing this document. Participation in this study is voluntary.

Disclaimer: Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive/health information about you or your child via e-mail.
Financial disclosure: The principal investigator and the University of Manitoba are receiving funds from Canadian Institutes of Health Research and the Canadian Cancer Society to conduct this study.

Background and Purpose

While there is growing evidence that Medical Cannabis may be an effective treatment option for patients suffering from chronic medical conditions, research on medical cannabis has focused primarily on the short-term response, with limited attention to long-term benefits of specific strains, dosing regimens or treatment modalities. Almost all of the research has focused on adult patients and their conditions. We will use caregiver reported outcome measures that reflect health outcomes relevant to specific medical issues (e.g. pain, sleep, mood, behaviour, seizures, treatment of cancer, or to manage symptoms related to cancer or cancer-treatment), as well as general quality of life for your family. We want to learn how these outcomes change overtime as you choose new products to help your child's health concerns over the next two years. Your child does not need to remain on cannabis to be a part of this study and you are able to change your product/dosing based on the advice of your child's health care provider and your child's preferences.

The goal of our research study is:

1. To describe patterns of cannabis use for medical purposes among pediatric patients authorized for medical cannabis in Canada
2. To investigate signals of benefit on the following outcomes: pain, sleep, anxiety, depression, positive affect, behaviour, cancer symptom burden, cachexia (extreme weight loss and muscle wasting), epilepsy (quality of life, side effects, and seizure frequency/severity), and family-related quality of life in a cohort of pediatric patients authorized for use of medical cannabis
3. To characterize the frequency and severity of cannabis-related adverse events and serious adverse events in pediatric patients authorized for MC use

For this study we are asking:

1. Your permission to use data (de-identified[1]) that you enter into an electronic platform that has been developed by the University of Manitoba
2. You to fill out online questionnaires related to your child's medical history, medication usage, pain, sleep, mood (anxiety, depression and positive affect), behaviour, cannabis use, and indication-specific outcomes as applicable (i.e., cancer, epilepsy)

We plan to enroll up to 500 pediatric participants from across Canada.

Procedure

Your child has been authorized to use medical cannabis and you have been invited to participate in the study. This is an observational study and there are no study visits required. Your child will continue to see their regular health care provider(s). Following your consent,

[1] De-identified data means that it had all direct identifiers removed from patient data and allows organizations to share it without the potential of violating HIPAA. Direct identifiers that will be removed can include a patient's name, address, medical record information, etc.

your child will be registered into the study via Research Electronic Data Capture (REDCap), which is a secure web application for building and managing online surveys and databases.

Follow up questionnaires and reminders will be sent to you at 3 weeks, 6 weeks, 12 weeks, 18 weeks, 6 months, 12 months, 18 months, and 24 months to understand the progression of your child's symptoms over time. These questionnaires should take about 30-45 minutes to complete on REDCap. At baseline, there is an additional medical history questionnaire, and at the last time point (24 months) there is an additional survey about your experiences in the study. These two questionnaires will take another 5-10 minutes to complete.

Variable	Baseline	3 weeks	6 weeks	12 weeks	18 weeks	6 months	12 months	18 months	24 months
Informed consent/assent and medical assessment questionnaire	X								
Medication and therapy assessment questionnaire		X	X	X	X	X	X	X	X
Cannabis use assessment questionnaire		X	X	X	X	X	X	X	X
Pain impact	X	X	X	X	X	X	X	X	X
Pain intensity	X	X	X	X	X	X	X	X	X
Sleep quality	X	X	X	X	X	X	X	X	X
Anxiety	X	X	X	X	X	X	X	X	X
Depression	X	X	X	X	X	X	X	X	X
Positive affect	X	X	X	X	X	X	X	X	X
Behaviour	X	X	X	X	X	X	X	X	X
Family-related quality of life	X	X	X	X	X	X	X	X	X
Adverse events		X	X	X	X	X	X	X	X

All questionnaires will be self-administered and will be collected through REDCap . The REDCap platform been developed and is managed by the University of Manitoba. However, the study team will follow up with you regarding questionnaires and other study related issues via e-mail or phone calls.

Procedure for Participants in the <u>Oncology Cohort</u>:

The following procedure applies only if your child is using medical cannabis for the treatment of cancer, or to manage symptoms related to cancer or cancer-treatment.

Once you consent to participate, you will be invited to complete an enrollment medical assessment questionnaire which will ask about your child's medications, cannabis use, cancer diagnosis/history. You will also be asked to complete 2 additional questionnaires at each time point related to your child's cancer symptom burden and cachexia (extreme weight loss and muscle wasting). Each of these questionnaires will take an additional 5-10 minutes to complete.

Procedure for Participants in the <u>Epilepsy Cohort</u>:
The following procedure applies only if your child is using medical cannabis to treat their epilepsy symptoms.

Once you consent to participate, you will be invited to complete an enrollment medical assessment questionnaire which will ask about your child's medications, cannabis use, seizure history/classification, and epilepsy classification. You will also be given instructions for a seizure diary to keep track of your child's seizure frequency throughout the study period.

You will also be asked to complete 2 additional questionnaires at each time point related to your child's epilepsy side effects and seizure frequency/severity. Each of these questionnaires will take an additional 5-10 minutes to complete.

<u>Potential Risks</u>
There are no additional risks to participating in the study other than questionnaire fatigue. If at any time your questionnaire responses indicate that your child is severely or extremely anxious/depressed in response or you report any serious adverse events, your child's treating health care provider will be notified.

The risks and potential side effects to your child taking medical cannabis should have been discussed with your physician during the authorization process. If you would like more information on the potential risks and side effects of medical cannabis please contact your authorizing physician or visit the Health Canada website here:
https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/regulations-support-cannabis-act/consumer-information.html

There is a potential loss of confidentiality, which is explained below.

<u>Confidentiality</u>
If you decide to participate in this study, the study investigators and staff will only collect the information they need for this study. Records identifying your child will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines:

- The University of Manitoba, the sponsor of this study
- The research ethics board(s) who oversees the ethical conduct of this study

Information that is collected about your child for the study (called study data) may also be sent to the organizations listed above. The records received by these organizations may contain your child's personal health information. Personal health information is any information that could identify your child and includes their name, date of birth, address, e-mail address, and phone number. Any information that may indicate that a child is being harmed or at risk of harm would not be kept confidential and instead be disclosed to appropriate authorities. The use of virtual platforms, like any internet communication or storage and retention of information, involves privacy risks around access and disclosure of information. However, there are safeguards to reduce these risks (e.g., account registration, meeting passwords, disposal of records or devices on which information is stored).

In order to protect your child's privacy, the researchers will remove any information that may be used to identify them from any documents, and will use a specific study code number that is unique to them. Only this code number will be used on any information collected about your child, so that their identity as part of the study will be kept completely safe and private. Only the researchers will have the ability to know their study code number, and the list with the code number information will be password protected.

If the results of this study are published, your child's identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. We will be sure to share the study findings with you and share them on our website www.medcankids.ca.

Even though the likelihood that someone may identify your child from the study data is very small, it can never be eliminated. A copy of the consent form you sign to enter the study may be included in your child's health record. Your child's study data will not be used or shared with other researchers for future studies, even if the researchers remove any information that could directly identify you.

This is a multi-site study, where participants will be recruited from all across Canada. It is likely that there will be data sharing with research investigators and staff, who are involved in this study, from outside your study site.

The University of Manitoba will keep any personal health information about you in a secure and confidential location for 15 years. A list linking your study number with your name will be kept by the study investigator in a secure place, separate from your study file.

Benefits

Your child may not receive direct benefit from being in this study. Information learned from this study may provide needed information for parents/caregivers, patients, and clinicians about the effectiveness of medical cannabis products in the real-world setting.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting the relationship with your doctor and the treatment your child receives.

You have the right to withdraw from the study as well as the withdrawal of information collected about your child at any time. If you want to withdraw from the study, let the Principal Investigator or study staff know. The principal investigator may also remove you from the study if there is insufficient data or compliance.

If you decide to leave the study, the study information about you that was collected before you left the study will still be used.

Cost

You will be compensated $20 for completed questionnaires at each time point (i.e., baseline, 3 weeks, 6 weeks, 12 weeks, 18 weeks, 6 months, 12 months, 18 months, and 24 months) up to a maximum of $180.

Rights as a Participant

By signing this consent form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest

There are no conflicts of interest to declare related to this study.

Questions About the Study

Should you have any questions with regard to this research, you are urged to contact Dr. Lauren Kelly at (204) 272-3149 or the study coordinator at (204) 891-0032 or 833-532-1440 (toll-free) or c4t.canada@gmail.com.

If you have any questions about Medical cannabis, please contact your authorizing health care provider. If your child experiences any side effects to the medical cannabis product, you can report them to your authorizing health care provider, or the study coordinator who will report to the authorizing health care provider to ensure continuity of care.

If you have any questions about your rights as a research participant, please do not hesitate to contact the Bannatyne Research Ethics Board at the University of Manitoba by email at bannreb@umanitoba.ca or by phone at 204-789-3255. The Bannatyne Research Ethics Board at

the University of Manitoba oversee the ethical conduct of research studies. These individuals are not part of the study team. Everything that you discuss will be kept confidential.

Consent

Consent to Contact for Future Studies:

You are being asked for permission to be contacted in the future for participation in research projects. If you agree to be contacted in the future for research purposes, the research team may contact you within the next 5 years. Your decision to allow your information to be retained for research purposes is completely voluntary. While there may be no benefit to you, your information will help researchers to quickly identify individuals who may be suitable to participate in a research project.

I agree to be contacted in the future for participation in additional research projects that are related to medical cannabis where the research team will explain the project and ask if I am willing to participate at that time:
___Yes
___No
___Not sure – I have some questions I would like to discuss with someone

I agree to be contacted:
___As often as the research team wants to contact me within the next 5 years
___Not more than once a month
___Not more than once every 6 months
___Not more than once a year

I want to be contacted by:
Phone_____
Email_____
*Please provide your contact information of your choice

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

_____	_____	_____
Signature of Legal Guardian (Substitute Decision-Maker)	PRINTED NAME	Date

If your child is 12 years old and older, please have them fill out below

I reviewed the consent with my parent/legal guardian. The study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

_____	_____	_____
Signature of Child	PRINTED NAME	Date