



STUDY PROTOCOL

Recreational Cannabis Usage Among Young Adults Living with Diabetes: Protocol for a Mixed Methods Study

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ABSTRACT

Background: Canada is the second country in the world to legalize recreational cannabis (marijuana). Young adults are the highest users of cannabis. Recreational cannabis use may increase anxiety, depression, breathing problems, and weight in young adults in general and further result in poor control of sugar levels, increased consumption of carbohydrates, and poor self-management in young adults living with diabetes. There is limited research on the

influence of recreational cannabis usage on young adults living with diabetes.

Purpose: To explore the frequency of recreational cannabis usage, self-management behaviors and experiences of cannabis-related adverse events, to identify the factors encouraging recreational cannabis usage, and to determine the influence of recreational cannabis usage on self-reported health among young adults living with diabetes.

Methods: A sequential explanatory mixed method design will be used. The first phase will be a cross-sectional online survey in which quantitative data will be collected on the demographic and health/clinical characteristics,

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cannabis use patterns, and diabetes self-management of young adults living with diabetes who use cannabis. The second phase will involve the collection of qualitative data through telephone, semi-structured, one-on-one interviews. Potential participants will be recruited through study flyers, posters, and clinicians from two outpatient diabetes clinics in the province of Ontario, Canada.

Planned Outcomes: The findings from this study may provide useful information regarding the effects of recreational cannabis consumption on young adults living with diabetes. This, in turn, may provide guidance to healthcare providers on how to counsel, assist, educate, and support diabetes-related management through strategies and interventions for this patient population, contributing to patient health and safety.

Keywords: Cannabis; Self-management; Type 1 diabetes; Type 2 diabetes; Young adults

Key Summary Points

- There is limited research on the influence of recreational cannabis usage on young adults living with diabetes, highlighting the importance of addressing this gap in research and, in turn, informing clinical practice and contributing to patient health and safety.
- Young adults are the largest consumers of recreational cannabis. As such, it is important to understand the frequency of recreational cannabis usage, self-management behaviors, and experiences of cannabis-related adverse events, to identify the factors which encourage recreational cannabis usage, and to determine the influence of cannabis use on self-reported health among young adults living with diabetes.

BACKGROUND

Canada is the second country in the world to legalize recreational cannabis (marijuana) for persons 19 years of age and older. According to the results of the National Cannabis Survey [1], the prevalence of recreational cannabis usage is threefold higher among persons aged 15–24 years (18%) than among those aged 25 years and older (6%). Additional findings are that approximately 4.6 million (15%) Canadians aged 15 years and older reported cannabis usage in the last three months, among whom nearly half (7%) reported using cannabis for non-medicinal reasons [1]. Furthermore, in 2017/2018, cannabis was found to be the most common substance associated with hospitalization among young adults, accounting for nearly 40% ($n = 9089$) of hospitalizations [2]. The motives behind recreational cannabis usage among young adults are reportedly related to the experience of excitement (i.e., high sensation), social (e.g., in order to have fun with peers during social gatherings), coping (e.g., with anxiety, depression, and child maltreatment), conformity (i.e., to fit in with peers), and routine/habit [3–7].

Among young adults, cannabis is not only extensively used, but it also represents a health risk factor. Cannabis plants contain more than 545 known compounds; these are collectively known as cannabinoids [8] and contribute to the development of a range of physical and mental health conditions. Among the unique compounds found in cannabis plants is Δ^9 -tetrahydrocannabinol (THC), a psychoactive compound present at high levels that produces the “high” persons experience when consuming cannabis. THC is also associated with anxiety, depression, panic attacks, cardiovascular (i.e., high blood pressure) and respiratory (i.e., bronchitis and emphysema) symptoms, and exacerbation of underlying psychiatric disorders (i.e., bipolar disorder and schizophrenia). THC may also be associated with alterations in body mass index, caloric intake, and self-management behaviors among young adults living with chronic diseases [8–11].

The potentially negative influence of recreational cannabis usage on the health of persons living with diabetes raises concerns, particularly with the increasing prevalence of diabetes in the general population (10%) and specifically in the adolescent and young adult population in Canada [12, 13]. The Diabetes Canada Position Statement has recently been released following a rapid review of the literature [14]. The findings from the review noted that recreational cannabis usage is not recommended for persons living with diabetes as it has been associated with worsening glycemic control, higher glycated hemoglobin (HbA1c), worsening glycemic control and self-management behaviours (i.e., glucose monitoring, medication adherence, compliance with diet and physical activity instructions), increased diabetes-related life-threatening complications (i.e., diabetic ketoacidosis) [15–18], as well as emergency room visits and hospitalization to manage these acute complications [19]. Further, there is increasing empirical evidence suggesting that the consumption of cannabis may disrupt the neurodevelopmental processes in young adults. The disruption in the neurodevelopmental process has been found to contribute to increased cannabis-related dependence, mental health disorders (i.e., psychosis, anxiety, and depression), short- and long-term cognitive impairment (affecting self-control, learning, memory, and attention span), engagement in risky behavior (i.e., driving while under the influence of cannabis), dropping out of school, and not pursuing a higher level of education [20–24].

Empirical evidence also suggests that cannabis usage has economic impacts on the healthcare system. For example, there have been increased cannabis-associated emergency department (ED) and urgent care visits among young adults that use cannabis [25]. Increased cannabis-associated ED visits pose significant challenges for health professional trainees and healthcare providers (HCPs) who may lack the knowledge and skills to provide effective clinical management in the ED [26]. Although the Diabetes Canada position statement cautions the use of recreational cannabis among persons

living with diabetes, limited empirical evidence currently exists that supports their recommendations for young adults living with diabetes and the effects of cannabis use on diabetes-related disease outcomes. It is therefore essential to examine the frequency of cannabis usage and its contribution to self-management and health functioning among young adults living with diabetes. This is important because young adults are not only the largest group of cannabis consumers, but they are at great risk of experiencing more serious cannabis-related adverse effects and generally have poorer treatment outcomes than adults [27].

Objectives

The purpose of this study will be to investigate the frequency of recreational cannabis usage, self-management behaviors, and experiences of cannabis-related adverse events, as well as explore the motives for recreational cannabis usage and its influence on self-reported health, among young adults living with diabetes. The protocol for this research study is described in the following sections.

METHODS

Study Design

A sequential, explanatory mixed (quantitative–qualitative) methods design will be employed. In Phase 1, quantitative data will be collected, using a self-administered online survey, on the demographic and health/clinical characteristics of young adults with diabetes, as well as on their cannabis use patterns, diabetes self-management during cannabis use, and cannabis-induced diabetes complications. Phase 2 will involve the collection of qualitative data through telephone, semi-structured one-on-one interviews to attain a more comprehensive understanding of the motivations for cannabis use and the management of diabetes among young adults living with diabetes. Data will be collected over a 1-year duration commencing in the Fall of 2020.

Sample Selection

The target population for this study are young adults living with diabetes. The eligibility criteria include (1) 18–24 years of age; (2) diagnosis of diabetes (type 1 or type 2) for ≥ 6 months; (3) self-reported usage of recreational cannabis; and (4) able to read and write in English.

Potential participants will be recruited from two diabetes outpatient clinics located in the province of Ontario (Canada). Both clinics provide integrated care, through an interdisciplinary team, to persons living with diabetes. Patients attending the program have opportunities to participate in various diabetes-related research studies. The two diabetes outpatient clinics have a large patient population and, in turn, a large number of potentially eligible participants.

PHASE 1: QUANTITATIVE PHASE

Quantitative Sample Size

Collectively, the two outpatient diabetes clinics provide services to more than 300 young adults (18–24 years of age) living with diabetes per year. All potentially eligible young adults will be recruited to accrue 150 participants; this sample size represents 50% of the accessible population and is adequate to address the descriptive purpose of this study.

Measurements

A self-administered online survey will be used. The self-administered online survey consists of two sections. The first section focuses on the socio-demographic characteristics of participants. Standard questions pertaining to demographic characteristics are used to assess age (at visit and diagnosis of diabetes), sex, race, and level of education. The second section of the online survey focuses on clinical characteristics and uses standard questions and psychometrically sound instruments to assess cannabis use (type, frequency of use, duration, primary form, and method of ingestion of cannabis) patterns,

motives for using cannabis, and diabetes-self management behaviors.

Specific to the clinical characteristics, standard questions will include those on type of diabetes, diabetes duration, and current diabetes treatment plan (i.e., insulin, metformin). Participants are also asked about adverse events that resulted in the need for healthcare service utilization and if they thought the adverse events resulted from cannabis consumption. More specifically, the following data will be collected: (1) number and frequency of emergency room visits; (2) number and frequency of hospital admissions; (3) type of complication within the past 3–6 months, such as hypoglycemic or hyperglycemic episodes; diabetic ketoacidosis; cardiovascular-related (i.e., high blood pressure, fast heart rate), respiratory-related (i.e., bronchitis, emphysema, breathing issues), and mental health-related (i.e., anxiety, depression, panic attacks, and exacerbation of underlying psychiatric disorders) complications.

Specific to cannabis consumption and diabetes self-care management, three psychometrically sound instruments will be used: the Daily Sessions, Frequency, Age of Onset, and Quantity of Cannabis Use Inventory (DFAQ-CU), the Marijuana Motives Measure (MMM), and the Diabetes Self-Management Questionnaire (DSMQ). These are described below in detail.

Daily Sessions, Frequency, Age of Onset, and Quantity of Cannabis Use Inventory

The DFAQ-CU is a self-report instrument that comprises of 33 items anchored on a Likert-type scale. The instrument measures cannabis usage across six factors: (1) daily sessions; (2) frequency; (3) age of onset; (4) quantity of cannabis consumed; (5) quantity of cannabis concentrates consumed; and (6) quantity of cannabis edibles consumed [28]. The subscales scores are computed by summing the respective items' scores, with higher scores reflecting more cannabis usage/consumption. The items have demonstrated good internal consistency reliability ($\alpha = 0.76$ – 0.95) and good convergent, divergent, and predictive validity [28]. To our knowledge, this data collection tool has not been used in the context of Canada because of

the limited research being conducted in this area; however, this validated instrument will be pilot tested.

Marijuana Motives Measure

The MMM is a self-report instrument that comprises of 25 items anchored on a 5-point Likert-type scale, with response options ranging from 1 “almost never/never” to 5 “almost always/always”. The MMM measures five distinct motives for cannabis usage: (1) coping (i.e., to forget one’s worries); (2) enhancement (i.e., because it is fun); (3) social motives (i.e., it helps one enjoy social gatherings); (4) conformity (i.e., peer pressure); and (5) expansion (i.e., to explore myself) [6]. The score for each motive is computed as the mean of the respective items’ scores; with higher scores reflecting stronger endorsement of a particular motive for cannabis usage [6]. The items have demonstrated good internal consistency reliability (e.g., $\alpha = 0.85$) [3]. To our knowledge, this data collection tool has not been used in the context of Canada because of the limited research being conducted in this area; however, this validated instrument will be pilot tested.

Diabetes Self-Management Questionnaire

The DSMQ is a self-report instrument that comprises of 16 items anchored on a 4-point Likert scale, with responses ranging from 0 “does not apply to me” to 3 “applies to me very much” [29]. The DSMQ assesses self-care behaviors associated with glycemic control through four subscales: (1) Glucose management (GM); (2) Dietary Control (DC); (3) Physical Activity (PA); and (4) Health-Care Use (HU) [29]. The DSMQ consists of seven positively worded items and nine negatively worded items [29]. The total score is computed after reverse coding negatively worded items, with higher scores reflective of effective self-care behavior [29]. The DSMQ has demonstrated good internal consistency reliability (e.g., $\alpha = 0.77$ – 0.84) and validity [29, 30]. The DSMQ is a validated data collection tool that has been used to explore and examine diabetes self-management behaviors in the Canadian population and context.

Quantitative Data Collection and Recruitment Procedures

A convenience sampling method will be employed. Potential participants will be recruited during their routine visits for diabetes care at the respective clinics. Specifically, upon completion of the clinical visit, potential participants will be asked (by their respective HCPs) if they are interested in taking part in the study (using a standardized recruitment script). If potential participants express an interest, they will be provided with a study flyer that will contain additional information about the study along with a URL link that would direct them to a letter of information/consent form as well as the online survey. In addition to the study flyer, study posters (which contain tear-off tabs) will be posted throughout the respective clinics.

Quantitative Data Analysis

Participants’ responses will be entered into the Statistical Package for Social Sciences version 23.0 (SPSS 23.0; IBM Corp., Armonk, NY, USA). Descriptive and inferential statistics will be used to analyze the quantitative data. More specifically, descriptive statistical analysis (i.e., measure of central tendency and standard deviations) will be conducted to describe the sample with regards to personal and clinical characteristics, utilization of healthcare services, as well as frequency and duration of recreational cannabis consumption. Where appropriate, inferential statistics (i.e., *t*-test, Chi-square, and/or regression analysis) will be employed to examine the outcomes of interest. Further, the analysis will be done in subgroups for Type 1 and Type 2 Diabetes separately because the two groups may have different baseline psycho-social profiles.

PHASE 2: QUALITATIVE PHASE

Qualitative Sample Size

The qualitative phase will use an interpretive description methodology [31], which is an approach for qualitative research within an applied discipline where the objective is to understand a real-world issue and findings are meant to serve a target audience within a specific contextual setting [31]. Data will be collected through a semi-structured interview. In congruence with qualitative methods, a sample size of 12–20 participants is adequate for qualitative studies [32]. However, the final sample will be based on the presence of data saturation [32, 33]. To confirm the achievement of data saturation, a constant comparison will be performed.

Qualitative Sampling Technique

The collection and analysis of qualitative data will commence upon completion of the quantitative phase. Participants who complete the anonymous online survey will have the option to provide their contact information (e.g., phone number or email) if they would like to participate in a telephone, one-on-one, semi-structured interview to further elaborate on their perspectives, motivations for cannabis use, and experiences with recreational cannabis usage and diabetes self-management. A convenience sampling method will be employed which will draw on a sample representing the target population that is willing to participate and easily accessible [34].

Qualitative Data Collection

The researcher will connect with participants who provided their contact information by phone or email (based on the contact information shared) to explain the purpose of the interview, highlight confidentiality, inform them that the interviews will be audio-recorded for research purposes only, and remind them that participation is voluntary. The researcher will also send an electronic copy of the letter of

information and consent form to potential participants. Once written consent is obtained, the researcher will arrange a time convenient for participants to conduct a telephone, one-on-one, semi-structured interview. The semi-structured telephone interviews will take approximately 45–60 min, and participants will be afforded the opportunity to not answer questions they are not comfortable with or interested in discussing.

A telephone interview was selected because it reduces the cost associated with traveling, mitigates the physical distance between participants and the researcher, reduces the power and response bias (i.e., social desirability) between the researcher and participants, and maintains anonymity and privacy, particularly given the sensitivity of the research topic [35–39].

Semi-structured interviews based on a pre-set of list of open-ended questions [40, 41] will be employed to aid the researchers in understanding the motives for recreational cannabis usage and its influence on self-reported health among young adults. However, a finalized set of questions cannot be established as the questions will evolve based on the emergent themes and concepts from the interviews.

Qualitative Data Analysis

The interviews will be audio-recorded and transcribed verbatim. Identifiable information (i.e., participant name, name of healthcare institution) will be removed from the transcripts to ensure the audio-recordings cannot be traced and/or associated to any of the participants. The transcripts will then be uploaded into NVivo 11 (QSR International, Melbourne, Australia). Braun and Clarke's [42] six phases for inductive thematic analysis will be used: (1) familiarizing with the data; (2) generating initial codes; (3) searching for themes; (4) reviewing themes; (5) defining and naming themes; and (6) producing the report. Several steps will be employed to ensure trustworthiness: reflexivity, interview and stepwise techniques, peer-debriefing, investigator triangulation, and code-to-code procedures [43].

ETHICS

This research study will be conducted in accordance with the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans and the Declaration of Helsinki. Research Ethics Board Approval will be obtained from the institutions of the two outpatient diabetes clinics (Hamilton Health Sciences and Women's College Hospital) prior to commencing the research study. For Phase 1 of the study, study posters will be posted around the diabetes clinics, and study flyers will be provided to individuals who express an interest in the study (during clinic visits). For those that are interested, potential participants will be asked to access the URL (included in the study flyer and poster), which will include the online letter of information/consent form and survey. For those that access the link, information (presented at Grade 6 level of education and comprehension) will be provided that explains the purpose of the research study and what participation entails. Completion of the online survey, which will take approximately 20 min, will imply the participants' voluntary and informed consent.

Specific to Phase 2 of the study, participants that express an interest in taking part in the interviews will be asked to share their contact information at the end of the online survey. Of those that share their contact information, a member of the research staff will contact them to explain the qualitative phase of the study and provide them with the letter of information (either by mail or email, as per the potential participants' preferences); for those subsequently expressing interest, written informed consent for the interview and audio-recordings of the interviews will be obtained.

Participants may refuse to answer any questions or withdraw from the study at any point in time with no implications on the care received from the respective diabetes clinics. Confidentiality will be maintained by restricting access to participant information, completed online survey, and interview audio-recordings, which will not contain any identifiable participant information (e.g., name), and transcripts to the research team. The data will

be saved on password-protected and secured SPSS and NVivo databases.

DISCUSSION

Canada is the second country in the world to legalize recreational cannabis. Empirical evidence has shown that cannabis use among persons living with diabetes is associated with alterations in self-management behaviors, worsening glycemic control, and increased life-threatening diabetes-related complications. However, limited robust empirical evidence exists on the impact of recreational cannabis usage among young adults living with diabetes (Type 1 and 2 Diabetes), highlighting the importance of this study, particularly because young adults are the largest consumers of cannabis.

Study Strengths

The study has several noteworthy strengths. First, it will be the first study, to our knowledge, to provide robust empirical evidence regarding the influence of recreational cannabis usage among young adults living with diabetes in Ontario, Canada. The timing of this study is particularly important due to the recent legalization of recreational cannabis in Canada coupled with young adults being the largest consumers of cannabis. Second, this study will contribute to the paucity of empirical evidence that exists to date post cannabis legalization in Canada. The results, in turn, may inform the development of evidence-based guidelines that HCPs can use to counsel, assist, educate, and support diabetes-related management through strategies and interventions, thereby contributing to patient health and safety. Finally, the collection of both quantitative and qualitative data will allow for a comprehensive and complementary understanding of the phenomena of interest, the ability to address both confirmatory and exploratory research questions, and for robust data analysis.

Study Limitations

There are several limitations to this study. First, the data will be drawn from participants at a single point in time. Second, to assess recreational cannabis usage, data will be collected through self-report, potentially resulting in inaccurate, incomplete, and/or imprecise reporting from participants [36]. Finally, personal recall of substance use may influence how participants respond to questions, potentially introducing social desirability bias [44, 45].

CONCLUSION

To our knowledge this study is the first to investigate the frequency of recreational cannabis usage, self-management behaviors, and experiences of cannabis-related adverse events, as well as explore the motives for recreational cannabis usage and its influence on self-reported health, among young adults living with diabetes in the province of Ontario (Canada). This study is warranted post cannabis legalization in Canada due to young adults being the largest consumers of cannabis coupled with the paucity of research that exists in this area. A sequential, explanatory mixed methods design will be used in this study. The quantitative phase (Phase 1) will involve the collection of data using a self-administered online survey. The qualitative phase (Phase 2) will involve telephone, semi-structured one-on-one interviews to attain a more comprehensive understanding of the motivations for cannabis usage and the management of diabetes among young adults living with diabetes. The findings from this study will have implications on research and clinical practice; all of which contribute to patient health and safety.

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Specific to Phase 2 of the study, participants that express an interest in taking part in the interviews will be asked to share their contact information at the end of the online survey. Of those that share their contact information, a member of the research staff will contact them to explain the qualitative phase of the study and provide them with the letter of information (either by mail or email, as per the potential participants' preferences); for those subsequently expressing interest, written informed consent for the interview and audio-recordings of the interviews will be obtained. Participants may refuse to answer any questions or withdraw

from the study at any point in time with no implications on the care received from the respective diabetes clinics. Confidentiality will be maintained by restricting access to participant information, completed online survey, and interview audio-recordings, which will not contain any identifiable participant information (e.g., name), and transcripts to the research team. The data will be saved on password-protected and secured SPSS and NVivo databases.

Data Availability. The datasets during and/or analyzed during the current study will be available from the corresponding author on reasonable request.

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