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Self-directed intervention for problematic cannabis use

Submission date
26/07/2022

Recruitment status
No longer recruiting

Registration date
28/07/2022

Overall study status
Completed

Last Edited
12/12/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cannabis use disorder (CUD) affects about 9% of individuals who use cannabis at least once. Effective treatments are available, but only a small proportion of individuals with CUD will choose to attend formal treatment. Self-directed treatments have also been developed and found effective with other substances and behaviours. However, there is still a need for self-directed treatments that are effective for CUD. This study focuses on how well a self-directed intervention works at helping individuals reduce how often they use cannabis and how much cannabis they use.

Who can participate?
People over the age of 18 years from across Canada with problematic cannabis use who are not interested in attending formal treatment.

What does the study involve?
Participants are randomly allocated to either (a) receive a self-directed treatment workbook; (b) receive the treatment workbook in combination with a brief motivational telephone interaction; or (3) a waitlist control group. The workbook provides strategies for reducing or quitting cannabis use. The motivational telephone interaction helps increase a person's motivation for changing their cannabis use. The participant's cannabis use (days of cannabis use, quantity of cannabis) will be tracked for a 12-month follow-up period at 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Possible benefits for participants include help to reduce their cannabis use either through these interventions or by receiving information about other sources. There are no identified risks to the safety of participants. At all phases of the participants' involvement they will be free to access other forms of treatment for cannabis use disorder. Information about other resources will be included in the treatment workbook and will be available from any study personnel upon request. The results of this research will be important for informing policy-makers who are developing treatment systems.

Where is the study run from?
University of Calgary (Canada)

When is the study starting and how long is it expected to run for?
April 2019 to May 2022

Who is funding the study?
Canadian Centre on Substance Use and Addiction (Canada)

Who is the main contact?
Dr David Hodgins, dhodgins@ucalgary.ca

Contact information

Type(s)
Principal Investigator

Contact name
Dr David Hodgins

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1056431

Study information

Scientific Title
Promoting self-change in problematic cannabis use: a randomized clinical trial of a brief self-directed cognitive-behavioural and motivational intervention

Study objectives
Primary hypotheses:
1. Participants who receive the self-directed treatment package alone or in combination with a

brief motivational interview will show a greater reduction in the frequency and quantity of cannabis use at 3-month follow-up than participants in the waitlist condition.
2. Participants who received the treatment package in combination with the motivational interview will show the greatest reductions in the frequency and quantity of cannabis use than participants who received the treatment package alone. This difference is expected to be most pronounced from baseline to 3 months than between 3 and 6 months

Secondary hypotheses:
1. Participants who receive the self-directed treatment package alone or in combination with a brief motivational interview will show greater reductions in cannabis use-related problems, reductions in psychological distress, and increased quality of life than participants in the waitlist control condition at 3-month follow-up
2. Participants who received the treatment package in combination with the motivational interview will show the greatest changes in use-related problems, psychological distress, and quality of life across time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 25/11/2020, The University of Calgary Conjoint Faculties Research Ethics Board (Conjoint Faculties Research Ethics Board
Research Services Office, 2500 University Drive, NW, Calgary AB T2N 1N4, Canada; +1 (0)403 220 4283/6289; cfreb@ucalgary.ca), ref: 1692

Study design
Randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Problematic cannabis use in adults

Interventions
Participants are randomly allocated to either (a) receive a self-directed treatment workbook; (b) receive the treatment workbook in combination with a brief motivational telephone interaction; or (3) a waitlist control group. The blockrand package (Snow, 2020) in R version 4.0.3 (R Core

Team, 2020) is used to create stratified random assignments within randomly chosen block sizes of 3, 6, 9, and 12. Participants were stratified on gender and problem severity (Cannabis Use Disorders Identification Test-Revised [CUDIT-R] < 22 or > 23).

Changing your Cannabis Use Workbook:
The self-directed treatment workbook was developed from the most common cognitive-behavioural and motivational strategies that individuals who have successfully recovered from cannabis use disorder have reported utilizing (Stea et al., 2015). It includes four core modules: self-assessment, goal setting, meeting your goal, and maintaining your goal.

Motivational interview:
The motivational interview was modified from the well-validated manualized MI protocol for gambling disorder developed in the researchers' lab. The interviewer attempts to explore ambivalence and strengthen the participant's motivation for changing their cannabis use. The motivational interviewing approach is guided by five therapeutic principles: acceptance of the individual and recognition that ambivalence is a normal process; development of discrepancies between the individual's current behaviour and their goals or values; avoidance of argumentation; roll with resistance; and support the individual's self-efficacy.

The participant's cannabis use (days of cannabis use, quantity of cannabis) will be tracked for a 12-month follow-up period at 3, 6 and 12 months.

Intervention Type
Behavioural

Primary outcome measure
1. Frequency of cannabis use in the previous month, measured using the Cannabis Engagement Assessment (CEA), a self-report questionnaire of recent cannabis engagement that asks participants to report the days of cannabis use in the previous 30 days, measured at initial assessment and follow-up (3, 6, 12 months).
2. Quantity of cannabis use used in the previous month, measured using the CEA, which includes questions on the quantity of cannabis use across three modes of cannabis (dry leaf, concentrates, edibles), measured at initial assessment and follow-up (3, 6, 12 months)

Secondary outcome measures
1. Cannabis use-related problems, measured by the Marijuana Problem Scale at initial assessment and follow-up (3, 6, 12 months)
2. Psychological distress, measured by the Kessler Psychological Distress Scale (K10) at initial assessment and follow-up (3, 6, 12 months)
3. Quality of life, measured by the World Health Organization Quality of Life – 8 Item Scale at initial assessment and follow-up (3, 6, 12 months)
3. Self-rated improvement measured on a Likert scale of 0 - “nothing has changed” to 10 - “I reached my goal”at follow-up (3, 6, 12 months)

Overall study start date
01/04/2019

Completion date
16/05/2022

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Fluent in English
3. Perception of a cannabis use problem
4. A score of 13 or greater on the Cannabis Use Disorders Identification Test-Revised (CUDIT-R; Adamson et al., 2010)
5. Have used cannabis at least once in the past month
6. Not currently receiving any other treatment for cannabis use problems (including 12-step programs and any medical or psychological treatment where cannabis problems are addressed)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Total final enrolment
186

Key exclusion criteria
Currently involved in treatment (including 12-step programs and any medical or psychological treatment where cannabis problems are addressed)

Date of first enrolment
03/12/2020

Date of final enrolment
22/05/2021

Locations

Countries of recruitment
Canada

Study participating centre
University of Calgary
Calgary
Canada
T2N 1N4

Sponsor information

Organisation
Canadian Centre on Substance Abuse

Sponsor details
75 Albert Street, Suite 500
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Sponsor type
Charity

Website
http://www.ccsa.ca/Eng/Pages/default.aspx

ROR
https://ror.org/04wm4pe30

Funder(s)

Funder type
Charity

Funder Name
Canadian Centre on Substance Use and Addiction

Results and Publications

Publication and dissemination plan
1. Self-directed workbook and Intervention implementation documents will be produced. The intervention will have the capacity to be used in future research or made available to individuals who wish to recover with minimal support. Adoption of this workbook will also assist mental health professionals to bolster treatment services.
2. The intervention protocol will be made available to research teams and stakeholders.
3. The results will inform the legislation review regarding important elements of an integrated public health system.
4. Planned publication in a peer-reviewed journal

Intention to publish date
30/11/2022

Individual participant data (IPD) sharing plan
The deidentified datasets analysed during the current study are available upon request from David Hodgins (dhodgins@ucalgary.ca). Calculated outcome variables and deidentified baseline data will be made available upon request by other researchers for the purposes of future systematic reviews and meta-analyses (SPSS format). Informed consent was obtained by all participants. This data will be retained indefinitely. Recordings and transcripts of the motivational interviews will not be made available, as participants provided consent for only the research team to have access.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		02/10/2020	27/07/2022	No	No
Results article		22/11/2022	12/12/2022	Yes	No