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CANreduce 3.0 - a web-based self-help program for reducing cannabis use that explores the effectiveness of mindfulness and cognitive behavioral therapy approaches

Submission date
09/09/2021

Recruitment status
No longer recruiting

Registration date
09/09/2021

Overall study status
Completed

Last Edited
06/12/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
In European countries, including Switzerland, as well as in many states worldwide, cannabis is the most widely used psychoactive substance (a chemical known to change brain function) after alcohol and tobacco. Although approximately one in ten users develop serious problems of dependency, only a small number attend outpatient addiction counseling centers. The offer of a web-based self-help program could potentially also reach those users who hesitate to approach such treatment centers and help them to reduce their cannabis use.
This study will test the effectiveness of two versions of a web-based self-help intervention (program) in reducing cannabis use in problematic users. One version is based on classical therapy (cognitive behavioral therapy) and one is based on mindfulness. A third condition is a waiting list control group.

Who can participate?
Adults (aged 18 years or above) who can read and write in German and have used cannabis at least once a week during the last 30 days.

What does the study involve?
Participants are randomly allocated to one of three groups. The two intervention groups consist of a 6-week, web-based self-help program (CANreduce) with a consumption diary, eight modules designed to help people to reduce their cannabis intake based on the principles of motivational interviewing, self-control practices, and methods of cognitive behavioural therapy (arm 1) or a mindfulness-based therapy (arm 2). The waiting control group are placed on a waiting list; after 6 months they can start the program, too. All participants are followed up after 6 weeks, 3 and 6 months to see whether they have reduced their cannabis use.

What are the possible benefits and risks of participating?
A possible benefit to participation is using less cannabis. Possible risks include experiencing mild cravings and depression.

Where is the study run from?
Swiss Research Institute for Public Health and Addiction (ISGF) (Switzerland)

When is the study starting and how long is it expected to run for?
April 2020 to March 2024

Who is funding the study?
Swiss National Science Foundation

Who is the main contact?
Prof. Dr Michael Schaub, michael.schaub@isgf.uzh.ch

Study website
http://www.canreduce.ch

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20.4.17, 10001C_192301 / 1

Study information

Scientific Title
CANreduce 3.0 - Randomized controlled trial testing the effectiveness of two different versions (mindfulness and CBT) of an adherence-focused web-based self-help intervention to reduce cannabis use in frequent cannabis users

Acronym
CANreduce 3.0

Study objectives
Current study hypothesis as of 24/01/2022:
1. A web-based self-help program with focus on mindfulness (arm 1) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use in frequent cannabis users
2. A web-based self-help program with focus on cognitive behavioral therapy (arm 2) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use in frequent cannabis users
3. A web-based self-help program with focus on mindfulness (arm 1) is at least as effective as one with focus on cognitive behavioral therapy (arm 2) in frequent cannabis users.

Previous study hypothesis:
1. A web-based self-help program with focus on mindfulness (arm 1) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use in cannabis misusers
2. A web-based self-help program with focus on cognitive behavioral therapy (arm 2) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use in cannabis misusers
3. A web-based self-help program with focus on mindfulness (arm 1) is similarly effective as one with focus on cognitive behavioral therapy (arm 2) in cannabis misusers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2020, Ethics Committee, Faculty of Arts and Social Science, University Zurich (Institute of Psychology, Binzmühlestrasse 14, Box 22, 8050 Zurich, Switzerland; +41 (0)44 635 74 70; k.oberauer@psychologie.uzh.ch), ref: 20.4.17

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

https://www.canreduce.ch/teilnahmeinformationen

Health condition(s) or problem(s) studied
Frequent cannabis use

Interventions
Current interventions as of 24/01/2022:
The three-arm randomized controlled trial aims to test the effectiveness of a newly developed integrated mindfulness-based minimally guided self-help Internet intervention (Arm 1) and a cognitive-behavioral minimally guided self-help Internet intervention (reference product; Arm 2) with a control condition (Arm 3) in 630 individuals with frequent cannabis use. Moreover, we will explore similarities between the main intervention (arm 1) and the reference product (arm 2) for the effect size of the difference between the two study arms with confidence interval approaches including a priori set equivalence margin. In addition, the project intends to identify and compare relevant predictors of retention, adherence, and treatment outcomes for the two main intervention arms. The primary outcome is the number of days of cannabis use in the last 30 days.

Participants are randomly allocated to one of three arms:
1. Intervention 1: Web-based self-help program with focus on mindfulness
2. Intervention 2: Web-based self-help program with focus on cognitive behavioral therapy
3. Control group: Waiting list

CANreduce is an automated web-based self-help tool based on classical CBT approaches (expanded with mindfulness for this trial) for treating adults with frequent cannabis use. It will take 6 weeks and consists of a consumption diary, eight modules designed to reduce cannabis use based on the principles of motivational interviewing, self-control practices, and methods of cognitive-behavioural therapy (strategies for goal achievement, identifying risk situations, dealing with cannabis craving, dealing with relapses, working on needs, saying “no” to foster refusal skills, dealing with burdens, preserving achievements).

The control condition is a waiting list. After 6 months they will be given the opportunity to start the self-help program (study arm 1).

The masking technique will be single-blind, insofar that participants are only informed that "two different interventions" are being studied but not that they are mindfulness and CBT based. However, they will know if they have been assigned to the waiting list.

Once participants have completed their baseline assessment, they will be randomly assigned by a software-generated random number to one of the three groups.

Previous interventions:
The three-arm randomized controlled trial aims to test the superiority of a newly developed integrated mindfulness-based minimally guided self-help Internet intervention (Arm 1) and a cognitive-behavioral minimally guided self-help Internet intervention (reference product; Arm 2) with a control condition (Arm 3) in 630 individuals who abuse cannabis. Moreover, we will explore similarities between the main intervention (arm 1) and the reference product (arm 2) for the effect size of the difference between the two study arms with confidence interval approaches including a priori set equivalence margin. In addition, the project intends to identify and compare relevant predictors of retention, adherence, and treatment outcomes for the two main intervention arms. The primary outcome is the number of days of cannabis use in the last 30 days.

Participants are randomly allocated to one of three arms:
1. Intervention 1: Web-based self-help program with focus on mindfulness
2. Intervention 2: Web-based self-help program with focus on cognitive behavioral therapy
3. Control group: Waiting list

CANreduce is an automated web-based self-help tool based on classical CBT approaches for treating cannabis dependence. It will take 6 weeks and consists of a consumption diary, eight modules designed to reduce cannabis use based on the principles of motivational interviewing, self-control practices, and methods of cognitive behavioural therapy (strategies for goal achievement, identifying risk situations, dealing with cannabis craving, dealing with relapses, working on needs, saying “no” to foster refusal skills, dealing with burdens, preserving achievements).

The control condition is a waiting list. After 6 months they will be given the opportunity to start the self-help program.

The masking technique will be single-blind, insofar that participants are only informed that "two different interventions" are being studied but not that they are mindfulness and CBT based. However, they will know if they have been assigned to the waiting list.

Once participants have completed their baseline assessment, they will be randomly assigned by a software generated random number to one of the three groups.

Intervention Type
Behavioural

Primary outcome measure
Number of days of cannabis use in the last 30 days measured using self-report at baseline, after 6 weeks, and at 3 and 6 months follow-up.

Secondary outcome measures
Current secondary outcome measures as of 24/01/2022:
1. Cannabis use frequency and amount over the past 7 days according to the "time-line-follow-back" (TLFB) method
2. Consumption patterns (years of cannabis use, 30-day point prevalence of cannabis and CBD use, type of consumption)
3. Cannabis use (CUDIT-R)
4. Alcohol abuse (AUDIT-C)
5. Perceived Stress (PSS-10)
6. Comprehensive Inventory of Mindfulness Experience (CHIME)
7. Depression (PHQ-9)
8. Generalized Anxiety (GAD-7)
9. Client Satisfaction
10. Negative effects according to Rozental et al. (2016)
11. Mindfulness Attention Awareness Scale (MAAS)
12. Severity of Dependence Scale (SDS)
13. National Institute on Drug Abuse Screening (NIDA-ASSIST)
14. Drug Abuse Screening Test (DAST-10)

15. Adult ADHD Self-Report Scale (ASRS-V1.1)
Some measures are taken at baseline (all but 9 and 10), some after 6 weeks (1, 2, 3, 5, 9, 10, 11, 12) and some after 3 and 6 months follow-up (1, 2, 3, 4, 5, 7, 8, 11, 12, 13)

Previous secondary outcome measures:
At baseline, after 6 weeks, and at 3 and 6 months follow-up.
1. Cannabis use frequency and amount over the past 7 days according to the "time-line-follow-back" (TLFB) method.
2. Number of days of CBD use in the last 30 days
3. Cannabis use (CUDIT)
4. Alcohol abuse (AUDIT-C)
5. Perceived Stress (PSS-10)
6. Comprehensive Inventory of Mindfulness Experience (CHIME)
7. Depression (PHQ-9)
8. Generalized Anxiety (GAD-7)
9. Client Satisfaction
10. Adverse effects according to Rozental et al. (2016)

Overall study start date
01/04/2020

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/01/2022:
1. Cannabis use of at least once a week 30 days prior to study entry
2. At least 18 years old
3. At least weekly internet access and a valid email address and phone number
4. Informed consent (via a web form)

Previous inclusion criteria:
1. Cannabis use of at least once a week 30 days prior to study entry
2. At least 18 years old
3. At least weekly internet access and a valid email address

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

630

Key exclusion criteria
1. Current pharmacological psychiatric disease or history of psychosis, schizophrenia, bipolar type I disorder or significant current suicidal thoughts
2. Use of other pharmacological and psycho-social treatments for cannabis use disorders
3. Inability to read or write in German

Date of first enrolment
13/09/2021

Date of final enrolment
13/09/2023

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
Swiss Research Institute for Public Health and Addiction (ISGF)
Konradstrasse 32
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Sponsor information

Organisation
University of Zurich

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Sponsor type

Research organisation

Website
http://www.isgf.ch

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
Fully anonymized data will be shared with qualified and trusted individuals for further use upon request (for example, for individual-patient data metanalyses). michael.schaub@isgf.uzh.ch

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/03/2022	06/12/2022	Yes	No