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CANreduce 2.0 - comparing two differently optimized versions of a web-based self-help program to reduce cannabis use with each other and a waiting list

Submission date
18/08/2016

Recruitment status
No longer recruiting

Registration date
18/08/2016

Overall study status
Completed

Last Edited
21/04/2022

Condition category
Mental and Behavioural Disorders

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

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 (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 an adherence-focused guidance enhanced 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 an enhanced web-based self-help intervention (programme), an unenhanced web-based self-help intervention and a waiting list control in reducing cannabis use in problematic users.

Who can participate?
Adults (aged at least 18), able to 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 intervention group are given access to the adherence-focused guidance enhanced web-based self-help program (CANreduce). The active control group are given access to the unenhanced web-based self-help program. The waiting control group are placed on a waiting list; after 3 months they are given the opportunity to start the self-help program. CANreduce consists of 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. Participants can study all modules at their own pace and order. All participants are followed up 3 months after the study ends to see whether they have reduced their cannabis use.

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

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

When is the study starting and how long is it expected to run for?
July 2016 to December 2017

Who is funding the study?
Research Institute for Public Health and Addiction (ISGF) (Switzerland)

Who is the main contact?
Mr Manuel Amann

Study website
https://canreduce.ch

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016-00264

Study information

Scientific Title

CANreduce 2.0 - the effects of an adherence-focused guidance enhanced web-based self-help program, an unenhanced web-based self-help program and a waiting list control on cannabis use in problematic cannabis users: a randomized controlled trial

Acronym
CANreduce 2.0

Study objectives
1. Adherence-focused guidance enhanced web-based self-help for the reduction of cannabis use (study arm 1) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use
2. Unenhanced web-based self-help for the reduction of cannabis use (study arm 2) is more effective than the waiting list control condition (study arm 3) in reducing cannabis use
3. Enhanced web-based self-help (study arm 1) is more effective than unenhanced web-based self-help (study arm 2) in reducing cannabis use

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kantonale Ethikkommission Zürich (Ethics board of the canton Zurich), 04/07/2016, ref: BASEC-Nr. 2016-00264

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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

Interventions
Participants are randomly allocated to one of three arms:
1. Intervention group: Adherence-focused guidance enhanced web-based self-help program
2. Active control group: Unenhanced web-based self-help program
3. Waiting control group: Waiting list

CANreduce is an automated web-based self-help tool based on classical CBT approaches for treating cannabis dependence. It will consist 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). Participants can study all modules at their own pace and order, though a specific order will be advised.

The control condition is a waiting list. After 3 months their study phase is finished and they will be given the opportunity to start the self-help program. Furthermore, there will be an active control group which works with the unenhanced version of the self-help tool.

The masking technique will be single-blind, i.e. participants will not know if they work with the enhanced or unenhanced version (however, they will know if they have been assigned to the waiting list).

Once participants have completed their baseline assessment, they will be randomized by a computer program in a 1:1:1 ratio to 1 of 3 “parallel” groups, and this assignment will be automatically registered in the background database. As participants will see if they have been assigned to the waiting list, there is a risk that some might try to circumvent their assignment by registering another account in hope to end up in a different group. In case a participant surmounts the administrative hurdle, he nevertheless will be assigned to the same group for a certain amount of time, based on his IP-address.

Intervention Type
Behavioural

Primary outcome measure
Quantity and the number of days per week of cannabis use. Participants enter their cannabis consumption quantity and frequency into their consumption diary every week.

Timepoints of measures will be initial assessment, after 6 weeks and at 3 months follow-up.

Secondary outcome measures
1. Severity of cannabis dependence (SDS)
2. The use of alcohol, tobacco, and other non-cannabis illicit drugs (FDA)
3. Changes in depression, anxiety and attention deficit symptoms (CES-D, GAD-7 and ASRS-V1.1)
4. Post traumatic Stress Disorder (Short Screening Scale for DSM-IV)
5. Client satisfaction (ZUF-8)

Severity of cannabis dependence and the use of alcohol, tobacco, and other non-cannabis illicit drugs will be measured at initial assessment, after 6 weeks and at 3 months follow-up.

Changes in depression, anxiety, attention deficit symptoms and the Short Screening Scale for DSM-IV Post traumatic Stress Disorder will be measured at initial assessment and at 3 months follow-up.

Client satisfaction will be measured after 6 weeks.

Overall study start date
01/07/2016

Completion date
01/12/2017

Eligibility

Key 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
597

Total final enrolment
775

Key exclusion criteria
1. Current pharmacological psychiatric disease or history of psychosis, schizophrenia, bipolar type I disorder or significant current suicidal or homicidal 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
02/08/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Austria

Germany

Switzerland

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

Organisation
Research Institute for Public Health and Addiction (ISGF)

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Sponsor type
Research organisation

Website
http://www.isgf.uzh.ch

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Government

Funder Name
Research Institute for Public Health and Addiction (ISGF)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/01/2018		Yes	No
Results article		30/04/2021	05/05/2021	Yes	No
Results article	subgroup analysis	20/04/2022	21/04/2022	Yes	No