Internet Program for the Reduction of Cannabis Use

Submission date	Recruitment status	[X] Prospectively registered		
15/04/2013	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/04/2013	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
16/10/2015	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Cannabis is the most widely used illegal drug in Switzerland, other Western European countries, Australia and the USA. Most users consume cannabis for recreational purposes, only from time to time or on special occasions. However, some users smoke cannabis more frequently and in higher quantities. These users risk adverse physical and mental health effects. Moreover, there is a certain risk of addiction that can have various psycho-social consequences (like e.g. problems with partner, parents, at work etc.)

in Switzerland and its neighboring countries, treatment for cannabis use disorders like cannabis dependence is mainly provided by outpatient addiction treatment services. For many users these services are difficult to access. Some users also hesitate to get into face-to-face contact as they worry that this could have negative consequences such as stigmatization. In order to improve anonymous treatment and to provide free access to treatment access we have developed the Cannabis Control program.

Who can participate?

Cannabis users aged 18 and above, either sex, and who have smoked cannabis at least once per week in the past 30 days prior to enrolment in the study.

What does the study involve?

Participants will be randomly allocated to one of three groups:

Group 1: Participants will have three individual chat-counseling sessions based on motivational interviewing and cognitive-behavioral therapy approaches in combination with the web-based self-help intervention from Group 2.

Group 2: The web-based self-help intervention is based on classical cognitive behavioral therapy approaches for cannabis addiction, motivational interviewing approaches, and principles of self control.

Group 3: Classical waiting list.

For Group 1 and Group 2, there will be weekly reminder emails to login and fill out a consumption diary. Counseling sessions in Group 1 are provided by trained addiction counselors. Moreover, 8 specific modules to work through in a fixed order but time independent manner will

be offered to Group 1 and Group 2. Participants allocated to Group 3 will have the opportunity to participate in the web-based self-help intervention after the follow-up assessment. Follow-up measures will be assessed online and/or by telephone calls three months after enrolment.

What are the possible benefits and risks of participating?

Within the 6 week web-based Cannabis Control program, participants can learn to reduce and control their cannabis use.

Cannabis abstinence or possibly also strong reduction of the frequency and quantity of cannabis may cause withdrawal symptoms or adverse events. In case of serious withdrawal symptoms or adverse events, additional telephone contacts to professionals are provided. Additional costs resulting from these personal contacts are to be covered by the general health insurance that is compulsory for everybody in Switzerland.

Where is the study run from?

The Cannabis Control study has been set up by the Swiss Research Institute for Public Health and Addiction, a World Health Organization Collaborating Center for Substance Abuse, associated institute to Zurich University, Switzerland. The study will be conducted in close collaboration with ARUD, the leading outpatient addiction counseling organization in the Canton of Zurich, Switzerland.

When is the study starting and how long is it expected to run for? Recruitment in expected to start mid-2013. Participants will be enrolled for a period of two years.

Who is funding the study? The Swiss Office for the Coordination of Addiction Facilities infodrog (Switzerland).

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

Contact information

Type(s)

Scientific

Contact name

Dr Michael Schaub

Contact details

Swiss Research Institute for Public Health and Addiction (ISGF) Konradstrasse 32 Postfach Zurich Switzerland 8031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Chat-Counseling and Web-Based Self-Help versus Web-Based Self-Help Intervention versus Waiting List to Control Cannabis Use in Problematic Cannabis Users: A Randomized Controlled Trial

Acronym

Cannabis Control

Study objectives

It is hypothesized, that web-based interventions which are more interactive are more effective in reducing cannabis use in problematic cannabis users. Therefore we will test the following detailed study hypotheses:

- 1. Chat-based counseling in combination with web-based self-help for the reduction of cannabis use is more effective than the waiting list control condition.
- 2. Web-based self-help for the reduction of cannabis use is more effective than the waiting list control condition.
- 3. Chat-based counseling in addition to web-based self-help for the reduction of cannabis use is more effective than web-based self-help alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Canton of Zurich, Switzerland, 11th April 2013, ref: KEK-StV-Nr. 15/13.

Study design

Three arm randomized controlled web-based 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 the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Cannabis misuse and cannabis abuse

Interventions

This is a three arm randomized controlled trial. The intervention in the first arm consists of three individual chat-counseling sessions based on motivational interviewing and cognitive-behavioral therapy approaches in combination with the web-based self-help intervention from study arm two. The web-based self-help intervention from study arm two is based on classical cognitive behavioral therapy approaches for cannabis addiction, motivational interviewing approaches, and principles of self control. The third study arm consists of a classical waiting list.

Study arms 1-2 involve weekly reminder e-Mails to login and fill out a consumption diary. Counseling sessions in study arm one are provided by trained addiction counselors. Moreover, 8 specific modules to work through in a fixed order but time independent manner will be offered in study arms 1-2. Participants randomized to the waiting list will have the opportunity to participate in the web-based self-help intervention after the follow-up assessment. Follow-up measures will be assessed online and/or by telephone calls 3 months past registration.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The primary outcome is the quantity of weekly cannabis use (measured in number of predefined average standard joints per week according to a consumption diary).

Secondary outcome measures

- 1. Number of cannabis use days per week
- 2. Severity of cannabis use (CUDIT)
- 3. Severity of cannabis dependence (SDS)
- 4. Cannabis withdrawal symptoms (CWS)
- 5. Cannabis craving symptoms (CCS-7)
- 6. Other psychoactive substance use
- 7. Brief Symptom Inventory (BSI-18)
- 8. Health status (EQ-5D-L)
- 9. Treatment retention
- 10. Treatment satisfaction

Overall study start date

31/08/2013

Completion date

31/08/2015

Eligibility

Key inclusion criteria

- 1. Minimal age 18, either sex
- 2. At least once a week cannabis use in the past 30 days prior to study entry

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

267

Key exclusion criteria

- 1. Current serious psychiatric illness or history of psychosis, schizophrenia, bipolar type I disorder or significant current suicidal or homicidal thoughts
- 2. No other pharmacological or psycho-social treatment for cannabis use disorders at study entry
- 3. Inability to read or write in German
- 4. For women: pregnancy or breastfeeding

Date of first enrolment

31/08/2013

Date of final enrolment

31/08/2015

Locations

Countries of recruitment

Switzerland

Study participating centre

Swiss Research Institute for Public Health and Addiction (ISGF)

Zurich Switzerland 8031

Sponsor information

Organisation

Swiss Office for the Coordination of Addiction Facilities - infodrog (Switzerland)

Sponsor details

c/o Alwin Bachmann Eigerplatz 5 Postfach 460 Bern 14 Switzerland 3000

Sponsor type

Government

Website

http://www.infodrog.ch

ROR

https://ror.org/01qtc5416

Funder(s)

Funder type

Government

Funder Name

Swiss Office for the Coordination of Addiction Facilities - infodrog (Switzerland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/11/2013		Yes	No

Results article results 13/10/2015 Yes No