ICAN: effectiveness of an online training to reduce cannabis use; a randomised controlled trial.

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To test the effectiveness of an online self-help training with adherence focused guidance on reducing cannabis use and increasing treatment service utilization in a sample of frequent cannabis users in a RCT. Primary objectiveTo test if an internet-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49982

Source
ToetsingOnline

Brief title
ICAN

Condition

- Other condition

Synonym
heavy cannabis use, smoking weed

Health condition

overmatig cannabisgebruik

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: VWS met cofinanciering van het Trimbos-instituut

Intervention

Keyword: cannabis, eHealth, online training, SBIRT

Outcome measures

Primary outcome

1. Frequency of cannabis use: the number of smoking days in the past 7 days

assessed 6 months post-randomisation using the Timeline Followback method.

Secondary outcome

2. Quantity of cannabis used (grams) in the past 7 days assessed 6 months post-

randomisation using the Timeline Followback method.

3. Cannabis use related problems as measured using the Cannabis Use Disorder

Identification Test (CUDIT).

4. Severity of dependence (number of self-reported DSM-5 criteria met).

5. Number of serious attempts to quit or reduce cannabis (self-report). A

serious quit attempt is defined as one lasting at least 24 hours.

6. Help seeking attitude as measured using the Mental Help Seeking Attitudes

Scale (MHSAS). An additional questionnaire used in previous research on help

seeking attitudes among frequent cannabis users is also include.

7. Number of participants that entered specialised drug treatment 6-months post

randomization (self-report).

8. Quality of life as measured with SF-6D.

9. Treatment satisfaction as measured with the Dutch version of the ZUF-8.

10. Demographics: age, sex, level of education.

11. Substance use (tobacco, alcohol, cocaine, amphetamine, inhalants, sedatives, hallucinogens, opioids and other drugs).

12. MCSDS: Marlowe Crowne Social Desirability Scale will be included to evaluate the reliability of the self-reported questionnaire data.

13. TiC-P: Direct non-medical cost data and productivity will be measured.

14. Number of self-reported cannabis withdrawal symptoms.

15. Marijuana Craving Questionnaire Short Form (MCQ-SF) will be included to assess craving for cannabis.

16. The Brief Symptom Inventory 18 (BSI-18) will be included to assess symptoms of anxiety and depression.

17. Self-efficacy to become or stay a non-smoker and resist cannabis will be measured by 6 items used in previous research.

18. The Cannabis self-concept scale will be included to assess identification with cannabis as part of the participant*s personality or identity.

19. Utilization variables will be collected during use of the intervention: number of logins, number of page views, time spend logged in, use of major content elements (i.e. exercises).

20. Knowledge questionnaire to assess obtained knowledge about CBT principles.

21. Knowledge questionnaire to assess obtained knowledge about treatment options/referral to treatment.

22. The effect of the coronavirus and the coronavirus measures on cannabis use and attempts to reduce/quit cannabis use will be measured by 7 items.

Study description

Background summary

It is estimated that almost 1% of European adults uses cannabis daily or almost daily. Regular cannabis use is associated with various adverse (mental) health effects. Regular cannabis users are at risk for dependence. There are effective treatments available for cannabis users. However, the majority of cannabis users does not seek help. Internet-delivered interventions have several advantages over traditional face-to-face treatments. Online interventions are characterized by a high degree of anonymity, this minimizes the fear of being stigmatized. Besides, they are easily accessible. Several online interventions for cannabis users have been developed. In a recently published meta-analysis on computerized interventions to reduce cannabis use, results showed a small but significant effect in favour of computerized interventions compared to control conditions. Thus, online interventions for cannabis use are effective and have several advantages over face-to-face treatments. Therefore, they may have the potential to improve treatment utilization among regular cannabis users. It remains unclear whether online interventions are able to motivate cannabis users to utilize specialized treatment services. Increasing drug treatment utilization also does not appear to be an explicit goal of the existing cannabis interventions. Given the low numbers of cannabis users entering treatment, it seems important to focus on increasing motivation to enter treatment. Interventions that aim to increase drug treatment utilization are often based on the principles of the Screening Brief Intervention and Referral to Treatment (SBIRT) approach. This research project aims to evaluate the effectiveness of an online self-help training with adherence focused guidance for cannabis users to motivate and support them to stop or reduce their cannabis use and to refer them to treatment. The online training, a progressive web app, is based on the principles of the Screening Brief Intervention and Referral to Treatment (SBIRT) approach.

Study objective

To test the effectiveness of an online self-help training with adherence focused guidance on reducing cannabis use and increasing treatment service utilization in a sample of frequent cannabis users in a RCT.

Primary objective
To test if an internet-based self-help training (screening, personalized feedback, brief intervention and referral to treatment) for reducing cannabis use shows favorable effectiveness (effect size d =.40) compared to the control condition (screening, feedback, online information brochure) on cannabis use 6 months post-randomisation.

Secondary objective
To test if an internet-based self-help training for reducing cannabis use shows favorable effectiveness compared to the control group, on attitudes toward seeking help for cannabis use related problems 6 months after randomisation.

Study design

A double blind randomized controlled trial will be carried out with a duration of 6 months in an online setting. The trial will be 2 armed (internet-based self-help training x online information brochure). Participants will be allocated in a 1:1 ratio to the two trial arms. Participants will be assessed on cannabis use related outcomes measures at T0 (baseline, before randomisation), T1 (6 weeks post-randomisation), T2 (3 months post-randomisation) and T3 (6 months post-randomisation). 267 participants will be included.

Intervention

The online training, a progressive web app, is based on the principles of the Screening Brief Intervention and Referral to Treatment (SBIRT) approach. The brief intervention component is based on cognitive behavioral therapy and motivational interviewing techniques.

Study burden and risks

Burden associated with the study is expected to be limited as the complete study will take place over the internet. The 6 week, 3- and 6-month post-randomisation questionnaires will be as short as possible. Participants only need a smartphone for all interactions (research and training) and can access the training whenever it suits them.

The control group receives information regarding cannabis moderation/cessation. The experimental group will receive access to an online self-help program/training which focuses on reducing cannabis use. Participants will be randomised to either condition (control/experimental) which may induce inconvenience. They are fully informed about the randomisation procedure before providing consent to participate in the study. Participants are provided with a phone number and email address if they would like to ask a question related to the study. For medical questions or emergencies, the primary contact person will be their family doctor.

A potential risk associated with the intervention are mild withdrawal symptoms, for example craving. Information about withdrawal symptoms will be provided in both interventions (experimental and control).

The benefits of the training are a better understanding of one*s cannabis smoking behaviour and help-seeking behaviour. The benefit for the study

population is that through acquiring knowledge regarding the effectiveness of internet-based self-help and referral to treatment, healthcare for cannabis users can be improved. All in all, we think those benefits outweigh the limited risks associated with this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age 18+
-Cannabis use on 3 or more days a week in the past month
-Desire to reduce or quit cannabis use
-Smartphone available
-Ability and intention to participate in the intervention and study for the period of 6 months

-Informed consent provided

Exclusion criteria

-Formal treatment (psycho-social or pharmacological) for cannabis use or any other substance use in the past 3 months
-Insufficient mastery of the Dutch language
-Self-reported suicidal ideation, acute psychosis or severe depression
-Pregnant or lactating

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-12-2019
Enrollment:	267
Type:	Actual

Medical products/devices used

Generic name:	a mobile application / training to stop or reduce cannabis use
Registration:	No

Ethics review

Approved WMO Date:	28-03-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-06-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25559
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67449.100.18
OMON	NL-OMON25559