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Integrative Cessation Program for co-smokers of cigarettes and cannabis

Submission date
28/02/2013

Recruitment status
No longer recruiting

Registration date
12/03/2013

Overall study status
Completed

Last Edited
17/11/2014

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
The relationship between tobacco and cannabis use is multi-layered, but current cessation programs usually focus on one substance while addressing the other substance marginally or not at all. Therefore we developed the first integrative group cessation program for co-smokers of cigarettes and cannabis that will be tested for feasibility (acceptance, safety, etc) and effectiveness (e. g. how many participants succeed in abstaining from cannabis and tobacco during the program and in the longer term).

Who can participate?
Co-smokers of tobacco and cannabis can take part that have a minimal age of 18, either sex, smoke at least five cigarettes per day in the past 30 days to study entry, and who at least once a week used cannabis in the past 30 days prior to study entry.

What does the study involve?
In this program, all participants can learn the same program to abstain from tobacco and cannabis use facilitated by specifically trained psychologists and psychiatrists within 2 months.

What are the possible benefits and risks of participating?
Co-abstinence of tobacco and cannabis is difficult to reach by oneself without professional help. Therefore participants receive professional help in groups of 8 to 12. Tobacco and cannabis abstinence may cause withdrawal symptoms or adverse events. In case of serious withdrawal symptoms or adverse events, additional therapy is provided.

Where is the study run from?
The study is lead by the Swiss Research Institute for Public Health and Addiction, an associated institute to Zurich University and a World Health Organization (WHO) collaborating center for substance abuse.

When is the study starting and how long is it expected to run for?
The study started in February 2012 and will run until April 2013. Participants will be recruited within this time period.

Who is funding the study?
The study is funded by the Swiss Tobacco Prevention Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Dr Michael Schaub

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09.008182

Study information

Scientific Title
Feasibility study of a Integrative Smoking Cessation Group Program for adult co-smokers of cigarettes and cannabis

Acronym
i-cut

Study objectives
The relationship between tobacco and cannabis use is multi-layered, but current national and international cessation programs usually focus on one substance while addressing the other substance marginally or not at all. This study investigates the feasibility and preliminary efficacy of an integrative smoking cessation program for adult co-smokers of cigarettes and cannabis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Canton of Zurich, Switzerland, 27/06/2011, ref: KEK-StV-Nr. 23/11

Study design
Interventional feasibility study
Cross sectional clinical cohort study

Primary study design
Interventional

Secondary study design
Cohort study

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
Nicotine dependence and cannabis misuse/abuse

Interventions
The study is taking place in two different addiction outpatient treatment sites.

The course is structured into six weekly sessions and one revival meeting about six weeks after the last session. Each of the sessions lasts between 90 and 120 minutes. Additionally, the course facilitators offer every participant one individual counselling session on request.

Subsidiary elements of the course sessions are a smoking diary and a workbook, which are introduced and distributed to the participants in the first session. The workbook contains background information, an overview of the course structure and contents, and work sheets to reflect on personal reasons for cessation and to develop and write down personal strategies. The smoking diary is a small notebook which can be easily carried to constantly monitor consumption, but also thoughts, feelings and actions associated with the use of one or both of the substances. Participants measure their expired carbon monoxide at every session to gain an objective feedback on their therapy progress and for later program evaluation. They can enter their individual values in their notebook and thus monitor the changes in the values.

The main goal of the intervention is dual abstinence of tobacco and cannabis. Carbon monoxide is assessed at every session. Further applied outcome measures are assessed at baseline, the last therapy session and at 6 months follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Frequency of tobacco and cannabis use in the last 7 days. Saliva samples are collected to assess cotinine levels at baseline, at the end of treatment, and at 6 months after the quit date for the biological validation of tobacco use.

Secondary outcome measures
1. Severity of nicotine and problematic cannabis use
2. Smoking attitudes
3. Depression (Beck Depression Inventory)
4. Anxiety measures (Beck Anxiety Inventory)
5. Cannabis and tobacco craving
6. Smoking cessation symptoms
7. A general health measure (SF12)
8. Smoking abstinence self-efficacy
9. Motivation to quit (according to the health action process approach for each and both substances together)
10. Other psychoactive substance use.
Moreover we will assess diverse course evaluation measures with the participants at the last session of their course. The course will be evaluated also in view of the course facilitators after the study intervention phase.

Overall study start date
01/02/2012

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Minimal age 18, either sex
2. Smoking at least five cigarettes per day in the past 30 days prior to study entry
3. 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
80

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. Use of bupropion or nicotine replacement therapy (NRT) or other smoking cessation treatment at study entry
3. Current behavioral treatments for cessation of marijuana or tobacco smoking
4. Inability to read or write in German

Date of first enrolment
01/02/2012

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
Swiss Research Institute for Public Health and Addiction ISGF
Zurich
Switzerland
8031

Sponsor information

Organisation
Swiss Tobacco Prevention Fund (Switzerland)

Sponsor details
Federal Office of Public Health FOPH
Hessstrasse 27E
Berne
Switzerland
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Sponsor type
Government

Website
http://www.bag.admin.ch/tabak_praevention/index.html?lang=en

ROR
https://ror.org/01qtc5416

Funder(s)

Funder type
Other

Funder Name
Swiss Tobacco Prevention Fund (Switzerland) grant number 09.008182

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?
Results article	results	12/09/2013		Yes	No