Drug addictions: marketing and brain activity

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Aim: This research will look at the implicit and explicit drug-related cognitions, at the effect of marketing cues on brain activity, and at the effect on aggressive behaviour, in alcohol users, cannabis users, and a control group. These effects…

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

Summary

ID

NL-OMON37814

Source
ToetsingOnline

Brief title
Marketing and brain activity

Condition

- Other condition

Synonym
agression and brain activity, cognitive motivational processes

Health condition

cognitief en emotioneel functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: FP7 EU

Intervention

Keyword: Alcohol, Brain activity, Cannabis, Marketing

Outcome measures

Primary outcome

Main study parameter: the implicit association cannabis and alcohol users have

with marketing cues of their drug, as measured with the Single Category

Implicit Association task (SC-IAT).

Secondary outcome

Secondary study parameters:

Activation of the reward neurocircuitry in the brain as measured with the BOLD

response in the fMRI -scanner.

Aggressive behaviour as measured with the point-to-subtraction task and

aggression SC-IAT.

Study description

Background summary

Rationale: First, drug-related cognitions have been implicated in the aetiology and maintenance of drug abuse. Second, research has shown that marketing has a significant effect on the consuming patterns of alcohol and tobacco users. Third, a relation between drug use and aggressive behaviour is often suggested.

Study objective

Aim: This research will look at the implicit and explicit drug-related cognitions, at the effect of marketing cues on brain activity, and at the

effect on aggressive behaviour, in alcohol users, cannabis users, and a control group. These effects will be investigated during abstinence as well as during intoxication in the alcohol and cannabis group. Subjects from the control group will not receive a treatment.

Study design

Study Design: double blind, placebo controlled, mixed design.

Intervention

Alcohol users will receive single doses of alcohol and placebo; cannabis users will receive single doses of cannabis and placebo; the control group will not receive any treatment.

Study burden and risks

Total amount of invested time for each subject is about 16 hours (8 for control subjects). A medical screening will take place, inlcuding an electrocardiogram (ECG), urine and blood analyses. Each testday will last about 6 hours. Subjects have to meake sure to get a good nights rest before each test day. Also they are not allowed to use cafeine of alcohol 24 hours prior to each testday. Cannabis users are not allowed to use cannabis 5 days prior to each test day.

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

Regular alcohol users: as using on average 21 to 50 alcoholic drinks/week for males or 15 to 35 alcoholic drinks/week for females during the last year, drinking alcohol both during the week as during the weekend ;- Regular cannabis users: having used cannabis at least 3 times a week but no more than 10 times a week, during the previous year. ;- Controls not currently using cannabis, experimental use of cannabis is allowed if it is more than a year ago and not more than 5 times in total. Alcohol use should be between 1 and 14 consumptions a week for men, and between 1 and 7 for women.;For all groups:;Age between 18 and 40 years;Free from psychotropic medication;Good physical health as determined by medical examination and laboratory analysis;Absence of any major medical, endocrine and neurological condition;Normal weight, body mass index (weight/height2) between 18.5 and 28 kg/m2;Written Informed Consent

Exclusion criteria

History of drug abuse (other than the use of cannabis for the cannabis group and alcohol for the alcohol group) or addiction (determined by the medical questionnaire, drug questionnaire and medical examination);Pregnancy or lactation;Hypertension (diastolic> 90; systolic> 140);Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination);Liver dysfunctioning;(Serious) side effects to previous cannabis or alcohol use;History of cardiac dysfunctions (arrhythmia, ischemic heart disease,*);For women: no use of a reliable contraceptive

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2012
Enrollment:	66
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bedrobinol
Generic name:	dronabinol/THC
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	08-08-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	10-10-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-001516-29-NL
CCMO	NL40475.068.12