ISRCTN25526593 https://doi.org/10.1186/ISRCTN25526593

Effects of neurofeedback on Cannabis Use Disorder (CUD)

Submission date
14/11/2017

Recruitment status
No longer recruiting

Registration date
01/12/2017

Overall study status
Completed

Last Edited
23/11/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cannabis use disorder (CUD) is the continued use of cannabis despite clinically significant distress or impairment. To date, CUD is mainly treated with motivational and cognitive-behavioral based methods. Additional approaches are needed to increase treatment effects. New knowledge on the brain alterations associated with addiction could be harnessed to guide treatment. Electroencephalogram (EEG) based neurofeedback (NFB) is a brain-computer interface method that has shown promises for treatment of substance use disorders. The aim of this study is to examine the effect of NFB as an additional treatment to conventional treatment (treatment as usual) on the levels of cannabis use and dopamine levels in the brain. The study also aims to compare patients with CUD and healthy volunteers using psychological tests, and to assess the normalization of these measures in patients after treatment.

Who can participate?
Patients aged 18 to 50 with CUD, and sex and age-matched healthy volunteers

What does the study involve?
Patients with CUD are randomly allocated to an experimental or a control group. The experimental group receive thirty 30-min sessions of EEG-based NFB in addition to treatment as usual over a 2-month period. The control group receive only treatment as usual. Treatment as usual in both groups consists of individual outpatient treatment on a weekly basis. Participants undergo tests of factors associated with addictive disorders such as impulsivity. In addition, in order to assess possible changes and their relation to brain dopamine function, participants undergo a PET scan. A control group of people without CUD is also included in order to compare at the start of the study patients with CUD and participants without CUD, particularly in relation to dopamine function. For CUD patients, participation involves five assessments (including two PET scans) and 2 months of treatment as usual with or without NFB. For control participants, the study involves one PET scan and assessments at the start of the study.

What are the possible benefits and risks of participating?
Patients with CUD and healthy volunteers will benefit from extensive psychiatric tests and brain scans. The scans can be used for later reference in case of a suspected brain disorder. People with CUD will benefit from TAU. The risks associated with this study can be considered minimal

to the overall health of the participants. The study involves injection of an (approved) radioactive tracer for PET scanning. NFB behavioral training with visual stimuli has a risk that is comparable to working on computer or playing video games.

Where is the study run from?
Geneva University Hospitals (Switzerland)

When is the study starting and how long is it expected to run for?
May 2017 to May 2019

Who is funding the study?
The HUG (Geneva University Hospitals) Private Foundation (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2017-00391

Study information

Scientific Title
Neurofeedback for Cannabis Use Disorder: a pilot study on clinical effects and possible relationship with brain dopamine function

Study objectives
Null Hypothesis (Ho): The mean changes in levels of cannabis use between before and after Neurofeedback (NFB) + Treatment as usual (TAU) are similar to those measured after TAU alone
Alternative Hypothesis (H1): The mean changes in levels of cannabis use between before and after NFB+TAU are different to those measured after TAU alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission Cantonale d'Ethique de la Recherche-Geneve, 24/05/2017, ref: CCER-Geneve. Approval: 2017-00391

Study design
Pilot randomized parallel-group open controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cannabis use disorder

Interventions
This is an pilot, randomized, parallel-group, open controlled study that aims to compare the effects of EEG-NFB as an additive intervention to conventional treatments (treatments as usual: TAU), on levels of cannabis use, drug craving, anhedonia in patients with a cannabis use disorder. The study is thus designed with two parallel treatment groups of patients with CUD for the evaluation of the two treatments. Patients with CUD will be randomly assigned to an experimental (n=17) or a control group (n=17). Concealed randomization will be made by an independent research assistant using sequentially numbered, opaque, sealed envelopes. The envelopes will each receive a number in advance (from 1 to 30), and will be opened sequentially, only after the participant's name is written on the appropriate envelope.

1. The experimental CUD group (or TAU+NFB group) will receive thirty 30-min sessions of EEG-based NFB in addition to treatment as usual (TAU) spread over a 2-month period. Each NFB session will consist of 30-minutes of training at home, with a frequency of 5 sessions per week
2. The control CUD group (or TAU group) will receive TAU only as a comparator. Standard TAU in both groups will consist of
individual outpatient treatment on a weekly basis

Follow-up assessment is planned at two months after the end last day of their respective treatment.

Moreover, the study will be complemented by a case-control group of 17 healthy volunteers (i.e. non-cannabis users) to directly investigate the abnormalities associated with CUD in terms of brain dopamine synthesis capacity, EEG spectral profile and neuropsychological variables related to impulsivity. The three tasks used in the present study to appraise different psychological patterns tied with impulsive behavior. Impulsive action is usually investigated using tasks that measure response inhibition such as the Stop-Signal Task whereas impulsive decision-making has primarily been investigates using the Delay Discounting Task. The Balloon Analogue Risk Task is used to assess real-word risk-taking propensity.

Intervention Type
Other

Primary outcome(s)
1. Cannabis use, measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)
2. DA synthesis capacity and storage, measured using [18F]-FDOPA Ki uptake values (6-fluoro-L-DOPA (or Fluorodopa)

Measured at baseline (including PET scan), within one week of the two months treatment (including PET scan) and at two months follow-up (excluding PET scan)

Key secondary outcome(s))
1. Time to smoke 1 gram of cannabis
2. Total scores on the Craving Experience Questionnaire and on the Dimensional Anhedonia Rating Scale
3. Theta/alpha power EEG measure
4. Stop-signal reaction time in the Stop Signal Task
5. Equivalence point in the Delay-Discounting Task
6. Average number of pumps delivered in the Balloon Analogue Risk Task

Measured at baseline (including PET scan), within one week of the two months treatment (including PET scan) and at two months follow-up (excluding PET scan)

Completion date
30/05/2019

Eligibility

Key inclusion criteria
1. 34 patients with DSM-5 Diagnosis of Cannabis Use Disorder (CUD)
2. 17 sex and age-matched healthy controls
3. Aged between 18 and 50 years inclusive
4. Informed consent
5. Available to complete the study
6. Negative serum pregnancy test at screening (for women of childbearing potential)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Psychiatric disorder (other than CUD in CUD patients)
2. Neurological disorder
3. Significant medical condition such as cancer, liver disease, hepatic impairment, renal disease, neuroleptic malignant syndrome, non-traumatic rhabdomyolysis, pheochromocytoma, or glaucoma
4. Current treatment with antipsychotic or benzodiazepine or monoamine oxidase inhibitor
5. Metal implant
6. Participation in a research/clinical study involving radiation exposure in the past 12 months
7. Pregnancy
8. Breastfeeding
9. Lack of safe contraception

Date of first enrolment
17/08/2017

Date of final enrolment
30/01/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Geneva University Hospitals
Switzerland
1202

Sponsor information

Organisation
Geneva University Hospitals - Addiction Unit

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

The HUG (Geneva University Hospitals) Private Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date