

Trial Description

Title

Randomized-controlled study on cognitive bias modification in adolescents with a focus on cannabis addiction

Trial Acronym

UNdope

URL of the trial

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Brief Summary in Lay Language

Cannabis abuse or rather addiction are one of the most frequent causes for detoxification in child and adolescent psychiatry. High relapse rates and chronic courses with severe limitations of social functions are common. Therefore, treatments which reduce the risk of relapse after detoxification are urgently necessary. Initial studies from alcohol research show that computer-assisted methods with the principle of cognitive bias modification (CBM) could be helpful. According to the CBM principle, the approach behavior with regard to an addictive substance is specifically reduced. The aim of the present study is to investigate the effects of a cannabis-approach-avoidance training (CAAT) on the approach tendency in cannabis-addicted adolescents compared to placebo training. A computer and app (tablet) assisted CAAT will be inserted in adolescent inpatients, who are in cannabis detoxification in the child and adolescent psychiatry, Hamm, Germany. We expect that the approach tendency in response to cannabis-associated stimuli will be reduced with the result that less cannabis craving or rather fewer relapses are observed after six trainings sessions and at follow-up three month later.

Brief Summary in Scientific Language

Cannabis abuse or rather addiction are one of the most frequent causes for detoxification in child and adolescent psychiatry. High relapse rates and chronic courses with severe social functional limitations are frequent. Therefore, interventions which reduce the risk of relapse after detoxification are urgently necessary. Initial studies from alcohol research show that computer-assisted methods, such as the "alcohol- approach -avoidance- training", with the principle of cognitive bias modification (CBM), could be helpful. The purpose of those trainings are to specifically reduce the approach behavior regarding an addictive substance. Recently, in alcohol research, the use of CBM-oriented training procedures has shown a reduction in approach behavior regarding alcohol-associated stimuli, with the result that fewer relapses were observed at follow-up one year later. Based on the promising findings from alcohol research, the aim of our study project is to investigate the effects of a cannabis- approach-avoidance training (CAAT) on the approach behavior of adolescents with cannabis addiction. So far, such interventions have not yet been inserted in cannabis-addicted adolescents in Germany. With a randomized controlled study design it is intended to evaluate the efficacy of a computer and app assisted CAAT for modifying attention control on



cannabis-associated stimuli compared to a placebo training. We hypothesize that after 6 trainings sessions and at follow-up three month later the approach towards cannabis-related stimuli will be significantly reduced in participants who receive the intervention training. We believe that due to the changes in the approach tendency in reponse to cannabis, fewer cannabis craving or rather less relapses will be observed.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012642**
- Date of Registration in DRKS: **2017/07/11**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **15-5878 , Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum**

Secondary IDs

Health condition or Problem studied

- ICD10: **F12.2 - Mental and behavioural disorders due to use of cannabinoids; Dependence syndrome**

Interventions/Observational Groups

- Arm 1: **Intervention training - Experimental group (EG):**
Participants randomly allocated to the experimental group will receive six CAAT sessions. In each session, 200 pictures with cannabis-associated and 200 pictures with neutral content are randomly displayed on the tablet (App) or computer screen. The pictures will be presented one by one and will be appear in a quasi-randomized order. In the EG condition the subjects push 100% of the cannabis pictures away (avoidance movement) and pull 100% of the neutral pictures to themselves (approach movement) (a wiping motion with the finger on the tablet or a joystick movement in the computer variant). In this way, the avoidance movement with regard to cannabis stimuli is trained specifically.



Pushing a picture away went along with a decrease in picture size, whereas pulling a picture closer resulted in an increased size (zoom-effect). Participants receive an implicit instruction - i.e. they must decide by the color of the picture frame whether they push or pull a picture. One picture category is always presented with a blue picture frame and the other picture category with a purple picture frame. In each training session participants receive the instruction to push pictures with one frame colour and to pull the pictures with the other frame colour. Every training session lasts at least 10 minutes, as this has been shown as an optimal training duration in previous studies.

■ Arm 2:

Placebo training - Control group (CG):

Participants randomly allocated to the control group (CG) will also receive six training sessions. As well as in the EG, in each session, 200 pictures with cannabis-associated and 200 pictures with neutral content are displayed randomly on the tablet or computer screen. The pictures will be presented one by one and will appear in a quasi-randomized order. Likewise as in the EG, participants receive an implicit instruction or rather have to orient themselves on the frame colour (blue or rather purple) of the pictures when pulling or pushing a stimuli. However, unlike the EG training, in the placebo training 50% of the cannabis-related images and 50% of the neutral images are pushed (avoidance), respectively 50% of the stimuli of both categories are pulled (approach). Both, the avoidance and the approach movement to cannabis-related stimuli are trained equally. Also equal to the EC are the variation in picture size during avoidance (push=decrease picture size) and approach (pull= increase picture size) movements as well as the duration of the each training session.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

The primary outcome is the change in the approach tendency towards cannabis-associated stimuli. For this, a "cognitive bias score" is calculated which subtracts the response time for approaching a cannabis-associated stimulus from the response time for avoiding a cannabis-associated stimulus. A positive value suggests a approach tendency regarding cannabis-associated stimuli, a negative

value suggests avoidance tendency.

The approach behavior towards cannabis-associated stimuli will be measured with an approach-avoidance task which is based on the AAT of Rinck and Becker (2007). In this task, which is performed on the computer or tablet app, the participants receive an implicit instruction - i.e. they must decide by the color of the picture frame whether they push or pull a picture. Pushing a picture away goes along with a decrease in picture size, whereas pulling a picture closer result in an increased size (zoom-effect). The present study will use two categories of pictures - 200 pictures with cannabis-associated and 200 pictures with neutral content are randomly displayed on the tablet or computer screen. One picture category is always presented with a blue picture frame and the other picture category with a purple picture frame. 50% of cannabis-related images and 50% of neutral images are pushed (avoidance movement), respectively 50% of the stimuli of both categories are pulled (approach movement) (like in the CG training). The pictures will be presented one by one and will appear in a quasi-randomized order. Participants start with 20 practice trials, followed by the 400 test trials. The AAT will be administered before training (pre), after six trainings sessions (post) as well as at follow up 3 months later to measure the approach and avoidance behavior. This AAT version is also used as control/ placebo training.

Another primary outcome is change in cannabis craving and cannabis consume (relapses).

The cannabis use and cannabis craving will be measured before the first trainings session, after the completion of the 6 training sessions and 3 months after the training (follow-up). The cannabis use disorder identification test (CUDIT, Adamson & Sellman, 2003) will be used for the measurement of cannabis use. The CUDIT is a screening questionnaire to assess the extent of harmful use of cannabis. Cannabis craving, on the one hand, will be measured with a visual analog scale with the endpoints 0 (currently no craving for cannabis) to 100 (currently a very strong craving for cannabis) and, on the other hand, with the Marijuana Craving Questionnaire (MCQ, Heishman et al.2001).

Secondary Outcome

The secondary outcome criteria are the changes in the clinical and addiction-related symptomatology . Before the fist trainings session, after 6 trainings sessions and three months after trainings completion the following clinical parameters will be measured with the following questionnaires:

Alcohol use: AUDIT- Alkohol Use Disorder Indentifikation Test (Saunders et al., 1993);

Nicotine use: FTND - Fagerstroem Test for Nicotin Dependence (Bleich, Havemann-Reinecke, & Kornhuber, 2002);

Cannabis consume: CUDIT - Cannabis Use Disorder Identifikation Test (Adamson & Sellman, 2003);

Marihuana Craving: MCQ- Marijuana Craving Questionnaire (Heishman et al., 2001);

Online behavior: OSVK-S - Scale of online addiction behavior in children and adolescents (Wölfling, Müller, & Beutel, 2010);

Sensation Seeking: NISS - Need Inventory of Sensation Seeking (Roth, Hammelstein, & Brähler, 2014);

Temperament and Charakter: JTCI- Junior Temperament and Charakter Inventory (Goth & Schmeck, 2009);

Abstinence confidence: HEISA-16 - Heidelberg scales for abstinence confidence (Körkel, & Schindler, 2004);

State of Change: VSS - Stages of change scale (Heidenreich, Hoyer, & Fecht, 2001);

**Depression: BDI- Becks Depression Inventory (Beck et al., 2006);
Sleeping behavior: PSQI- Pittsburgh Sleepquality Index (Buysse , Reynolds, Monk,
Berman, Kupfer, 1988);
Trauma: CROPS- Child Report of Post-Traumatic Symptoms (Greenwald & Rule,
1999);
Anxiety: STAI- State Trait Angst Inventar (Laux, Glanzmann, Schaffner, &
Spielberger, 1981).**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **LWL-Universitätsklinik Hamm der Ruhr-Universität Bochum,
Hamm**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/31**
- Target Sample Size: **144**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

primary diagnosis of cannabis addiction, inpatient treatment

Exclusion criteria

**Other primary substance use disorder, acute psychotic episode, low German
language skills**

Addresses



■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

**LWL Forschungsinstitut
44181 Bochum
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Private sponsorship (foundations, study societies, etc.)

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■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/05/28**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.