Trial Description

Title

Prevention of Substance Abuse and Mental Disorders in Children using the Mindfulness-Augmented “Trampoline” Program

Trial Acronym

TRAMP-MIND

URL of the trial

http://www.projekt-trampolin.de

Brief Summary in Lay Language

Children of substance-abusing parents (CSP) often develop alcohol or drug problems themselves or they suffer from other psychological problems. Especially CSP, which are in psychiatric treatment because of psychological problems at an early age, are at risk for own alcohol or drug problems and are therefore in need of prevention. Research results have shown that certain factors in the human brains influence self-control mechanisms which in turn can be related to alcohol or drug and other psychological problems. These factors as well as stress sensitivity can be positively affected by mindfulness practices. In our study, we will test whether an existing intervention for CSP between the age of 8 and 12, the “Trampoline” program, has even better effects on stress sensitivity and coping and on psychological problems if mindfulness elements are added to the program. We will compare this new version to the standard "Trampoline"-program on in total 420 CSP who are currently receiving psychiatric care and/or are integrated in a youth welfare setting and/or outpatient drug counselling services.

Brief Summary in Scientific Language

Children of substance-abusing parents (CSP) are at substantial risk to develop own substance use disorders (SUD) and other psychopathology. CSP not diagnosed with a SUD, but in psychiatric treatment or integrated in a youth welfare setting, constitute a particular high-risk group in need of SUD prevention. An emerging evidence base indicates that neurobehavioral, self-regulatory determinants of substance use and other mental disorders and particularly stress reactivity are modifiable by mindfulness-based interventions, such as Mindfulness-Based Stress Reduction. In this cluster-randomized-controlled trial we will test the hypothesis that a mindfulness-augmented version of the modularized evidence-based “Trampoline” program has a larger effect on adaptive stress coping strategies (primary outcome), internalizing and externalizing problem behaviors and distress due to parental substance use compared to the standard program version in a sample of 420 CSP who are receiving non SUD-specific psychiatric care and/or are integrated in a youth welfare setting. Mindfulness components will be regularly practiced for 30 minutes in each validated Trampoline module. Children included in the study will be 8 -12 years of age. We will also investigate feasibility of mindfulness-based interventions for affected children in the coentext of psychiatric hospital units,
inpatient youth welfare services and outpatient drug and alcohol counselling centres.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: DRKS00013533
- Date of Registration in DRKS: 2018/07/16
- 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.: [---]*, Katholische Hochschule Köln K2-Ethikommission

Secondary IDs

Health condition or Problem studied

- ICD10: F90-F98 - Behavioural and emotional disorders with onset usually occurring in childhood and adolescence
- ICD10: F10 - Mental and behavioural disorders due to use of alcohol
- ICD10: F19 - Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Interventions/Observational Groups

- Arm 1: Standard Trampoline program augmented by elements of mindfulness-based stress reduction training. The standard Trampoline program is a modularized program for children of substance-abusing parents aged 8-12 years including psychoeducation and practices to improve coping, stress reduction, self-esteem, and self-efficacy. This program will be augmented by mindfulness elements for children.
- Arm 2: Standard Trampoline program
- Arm 3: Non-intervention control group
Characteristics

- **Study Type:** Interventional
- **Study Type Non-Interventional:** [---]*
- **Allocation:** Randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
- **Control:** Active control (effective treatment of control group), Control group receives no treatment
- **Purpose:** Prevention
- **Assignment:** Parallel
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** N/A

Primary Outcome

Use of stress coping strategies (measured with Questionnaire for Assessment of Stress and Coping in Childhood and Adolescents (SSKJ 3-8) subscale), 3 times of measurements (between Dec 2018-Dec 2020)

Secondary Outcome

Stress symptoms (SSKJ 3-8 subscales), distress due to parental substance use (self-constructed items), internalizing and externalizing problem behaviors (parent reports in validated clinical questionnaire Strengths and Difficulties Questionnaire SDQ), neurobehavioral target measures; 3 times of measurement (between Dec 2018-Dec 2020)

Countries of recruitment

- DE Germany

Locations of Recruitment

- Medical Center DRK Krankenhaus Altenkirchen-Hachenburg, Altenkirchen
- other Stiftung Die Gute Hand Kürten-Biesfeld, Kürten-Biesfeld
- other Sachthilfe Aachen, "Feuervogel", Aachen

Recruitment
Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 8 Years
- Maximum Age: 12 Years

Additional Inclusion Criteria

Boys and girls exposed to regular parental (caregiver) substance abuse within the last 12 months, regular contact with substance-abusing parent(s)/caregiver(s) (min. 1 day/week), age 8 to 12 years at t0, positive CAST-6 (Children of Alcoholics Screening Test) screening, temporally situated in psychiatric day-care centers, psychiatric outpatient or inpatient treatment, inpatient youth welfare settings and/or outpatient alcohol or drug counselling services.

Exclusion Criteria

Participants suffering from fetal alcohol spectrum disorder (FASD), with cognitive impairment, severe conduct problems that might interfere with group participation, insufficient language capabilities, bipolar disorder or schizophrenia, participation in a substance-related intervention within the last 6 months.

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(German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

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Status

- Recruitment Status: Recruiting planned
- Study Closing (LPLV): [---]*

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.