

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Mechanisms of resilience against alcohol abuse in adolescents

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study aims to investigate factors that lead to increased alcohol consumption in adolescents. Furthermore, the mechanisms behind these factors will be analyzed, i.e. it will be examined how the factors lead to an increased alcohol consumption or how other factors protect against an increased alcohol consumption. Within the first part of this study, a brief questionnaire will be established, which will be answered by approx. 500 adolescents. Afterwards, selected adolescents will be examined in more detail by the use of neuropsychological tests and functional magnetic resonance imaging on their behavior in stressful situations.

Brief Summary in Scientific Language

Different risk factors such as genetic susceptibility and negative life events contribute to the development of mental disorders. However, resilient persons do not develop psychiatric disorders in face of those risk factors. By analysing both risk factors for the development of psychiatric disorders and protective factors against their development one can establish basic approaches for therapies and prevention. Thereby, the examination of adolescents is of high interest, because they are very vulnerable for the development of mental disorders. Thus, prevention may be very effective. Alcohol misuse of adolescents is a psychiatrically relevant behaviour which is associated to other mental disorders, as well. In this project, we want to identify resilience factors against alcohol misuse and their mechanisms to contribute to the development of preventive measures. Within the IMAGEN study we have access to psychological questionnaires, genetic material and functional brain data of more than 2000 adolescents over a long period. Therein we want to statistically establish the most important risk factors for the development of alcohol misuse and protective factors against it. Hence, we will develop a questionnaire containing the most important factors and questions on alcohol consumption. We will give this questionnaire to adolescents in Mannheim and surroundings and seek the return of 500 questionnaires. Thereby we will recheck the results of the statistical analyses out of the IMAGEN study and furthermore we will recruit participants for the following examination of the mechanisms of resilience. Therefore 60



adolescents will be invited for a detailed examination to the Central Institute of Mental Health. Three different groups will be recruited to determine the mechanisms of resilience and transition to harmful alcohol use: 1) a group of non-risk but heavy drinkers, 2) high-risk actual heavy drinkers, and 3) high-risk non-heavy drinkers. Participants will take part in a neuropsychological test battery including functional magnetic resonance imaging. Life situation of the high-risk groups will be very stressful but resilient adolescents might have developed strategies or possess mechanisms that lead to a differential reaction on stress. Thus, first of all we will analyse whether resilient adolescents can handle stress differently. We examine how these mechanisms are represented on a neural level, how they can be seen on the level of personality and which behavioural patterns occur that can be implemented for the development of new aspects in behaviour therapy and prevention measures.

Organizational Data

- DRKS-ID: **DRKS00008937**
- Date of Registration in DRKS: **2016/04/06**
- 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.: **2013-642N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- Free text: **alcohol misuse**

Interventions/Observational Groups

- Arm 1: **high alcohol consumption (low risk): selected adolescents will be examined in more detail by the use of neuropsychological tests and functional magnetic resonance imaging on their behavior in stressfull situations.**
- Arm 2: **high alcohol consumption (high risk) selected adolescents will be examined in more detail by the use of neuropsychological tests and functional magnetic resonance imaging on their behavior in stressfull situations.**
- Arm 3: **low alcohol consumption (high risk) selected adolescents will be examined in more detail by the use of neuropsychological tests and functional magnetic resonance imaging on their behavior in stressfull situations.**



Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Comparison of resilient adolescents and non-resilient adolescents, measured by Trier Social Stress Test for Children and Montreal Imaging Stress Test.

Secondary Outcome

We will analyse whether resilient adolescents can handle stress differently. We examine how these mechanisms are represented on a neural level (functional magnetic resonance imaging), how they can be seen on the level of personality (measured by gemessen: Neuroticism-Extraversion-Openness Five-Factor Inventory (NEO-FFI), Temperament and Character Inventory-Revised (TCI-R), Substance Use Risk Profile Scale (SURPS) und Multidimensional Assessment of Stressful Life Events among Adolescents: Derivation and Correlates (LEQ)) and which behavioural patterns occur (measured by Trier Social Stress Test for Children and Montreal Imaging Stress Test) that can be implemented for the development of new aspects in behaviour therapy and prevention measures.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Zentralinstitut für Seelische Gesundheit, Mannheim**

Recruitment

- Planned/Actual: **Actual**

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2015/12/23**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

participation is voluntary, adlosecents at the age 14-18

Exclusion criteria

participation is not voluntary, adolescents at the age < 14 or >18

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**

DRKS-ID: **DRKS00008937**

Date of Registration in DRKS: **2016/04/06**

Date of Registration in Partner Registry or other Primary Registry: [---]*

- 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.*