

Trial Description

Title

**Pregnant? Your child is drinking, too! Alcohol? Not a sip - not at risk!
Evaluation of a physician-led school-based intervention on fetal alcohol spectrum disorders (FASD) in a wait-list controlled study**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In Germany, 10.000 children are born each year with FASD (Fetal Alcohol Spectrum Disorders), displaying varying degrees of severity. This makes FASD, which is caused solely through maternal alcohol consumption during pregnancy, the most common non-genetic cause of congenital malformations, cognitive and psychological disabilities and growth- and developmental disturbances of children in Germany and many other countries.

Since FASD could be 100% avoided through abstinence from alcohol consumption during pregnancy, education and the creation of awareness are essential for FASD prevention within society.

This includes teenagers, since first experiences both in alcohol consumption and sexual behavior are made during this phase of life, partly in form of risky behavior, forming attitudes and establishing behavioral routines.

The Physicians' Organization for Promoting Health (ÄGGF) offers schools physician-led prevention sessions focusing on the topic "Pregnant? Your child is drinking, too! Alcohol? Not a sip - not at risk!" for classes 8th grades or higher. The goal of these sessions is to convey adequate knowledge about the symptoms and causes of FASD, emphasize the relevance of their own behavior for FASD prevention and to strengthen the intention to abstain from alcohol consumption in case of pregnancy.

This study now aims to investigate via questionnaire which effect a physician-led school-based FASD intervention has on the knowledge of symptoms and causes of FASD, as well as the students' intended consumptive behavior in case of pregnancy and how the session is rated by the teenagers.

Brief Summary in Scientific Language

Background and study aims:

Although Germany is a highly developed industry nation with excellent educational opportunities and medical care including prenatal care, 10.000 children are born each year with FASD (Fetal Alcohol Spectrum Disorders), displaying varying degrees of severity. This makes FASD, which is caused solely through maternal alcohol consumption during pregnancy, the most common non-genetic cause of congenital malformations, cognitive and psychological disabilities

and growth- and developmental disturbances of children in Germany and many other countries.

No threshold amount of alcohol can be determined which is guaranteed to be nonhazardous in the embryonal and fetal development of the child. Since FASD could be 100% avoided through abstinence from alcohol consumption during pregnancy, education and the creation of awareness are essential for FASD prevention within society. As adolescence is critical for establishing behavioral patterns, education and creation of awareness are already important for this age group.

This is why the Physicians' Organization for Promoting Health (ÄGGF) offers schools physician-led prevention sessions focusing on the topic "Pregnant? Your child is drinking, too! Alcohol? Not a sip - not at risk!" for classes 8th grades or higher. The goal of these sessions is to convey adequate knowledge about the symptoms and causes of FASD, emphasize the relevance of their own behavior for FASD prevention and to strengthen the intention to abstain from alcohol consumption in case of pregnancy.

In the accompanying study the acceptance and efficacy of these physician-led intervention sessions are to be evaluated in a wait-control-group study.

It is hypothesized that at the second assessment the students in the intervention group will, , in comparison to the first assessment,

- have a higher increase of knowledge**
- develop more critical attitudes towards alcohol consumption during pregnancy**
- display stronger intentions to remain completely abstinent in a future pregnancy / motivate their partner or other pregnant women in their environment to remain completely abstinent**
- give higher ratings for the relevance of the topic FASD than the students in the wait-control-group.**

Description of the intervention:

The physicians of the ÄGGF offer 90 minute informational sessions in school. During this session the physician conveys health information to students 8th grade or higher with emphasis on the topics FASD, pregnancy and the consequences of alcohol consumption during pregnancy. The physician orientates her session in accordance to the knowledge level and needs of the age group i.e. the students are free to ask questions for the physician to address further.

Methods:

The evaluation of the intervention is conducted using a cluster-randomized wait control-group study with two arms. The intervention and data collection is planned between December 2016 and July 2017 in a sample of approximately 2,500 students 8th grade or higher and will be recruited consecutively in four German federal states (Schleswig-Holstein, Berlin, North Rhine-Westfalia, Bavaria). Within the participating schools, the classes will be assigned randomly to the intervention or the wait-control group. The students in the intervention group receive the informational session directly after participating in the baseline assessment; the post-intervention assessment takes place 4-6 weeks later. In the wait-control group, the two assessments are conducted within the same time frame, but the intervention is implemented after the second assessment. During the assessments the students' knowledge about the symptoms and cause of FASD as well as their intended behavior in case of pregnancy is measured via questionnaire.

The questionnaires are filled out under instruction by the physician in the students' classroom setting and is completely anonymous, i.e. the name of the subject is not requested at any point. In order to match the baseline and the second assessment questionnaires, a 7-letter code is employed, which the students generate themselves and can be reconstructed anytime. It is not possible to construct the student's identity from this code.

The data collected in this study is handled confidentially. The data is scanned, saved and interpreted with the help of computer software. The data is not analyzed on the level of individual participants. In addition all participants or their legal guardians can retract their consent to participate in this study at any time and demand the deletion of their collected data.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011296**
- Date of Registration in DRKS: **2016/11/09**
- 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.: **RH_032105 , Ethikkommission der Deutschen Gesellschaft für Psychologie e.V.**
c/o Universität Trier Fachbereich I Psychologie
D-54286 Trier
Deutschland
<https://www.dgps.de/index.php?id=185>

Secondary IDs

Health condition or Problem studied

- ICD10: **Q86.0 - Fetal alcohol syndrome (dysmorphic)**
- Free text: **Alcohol use during pregnancy to avoid FASD**

Interventions/Observational Groups

- Arm 1: **Participation in a physician-led 90 minute informative session in the classroom: A physician visits the school class and informs students about sexual health, contraception, cause, symptoms and prevention of FASD. Assessment before and 4-6 weeks after the intervention**
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Arm 2: **Waiting-list control group; two assessments at an interval of 4-6 weeks followed by the intervention**

Characteristics

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

Primary Outcome

Immediately before the intervention and 4 to 6 weeks later the following variables are assessed in questionnaires with self generated and pretested items: Knowledge about the symptoms and cause of FASD, knowledge and intended behavior to avoid FASD (complete abstinence from alcohol during pregnancy)

Secondary Outcome

Equally immediately before the intervention and 4 to 6 weeks later attitudes towards substance use during pregnancy are assessed in a questionnaire.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Schulen ab Klassenstufe 8 in den Bundesländern Berlin, Nordrhein-Westfalen, Schleswig-Holstein und Bayern, [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/12/06**

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- Target Sample Size: **2500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Students grade 8 and up

Exclusion criteria

<8th grade

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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■ **Collaborator, Other Address**

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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.)**

Bundesministerium für Gesundheit

Friedrichstraße 108

10117 Berlin

Germany

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Friedrichstraße 108
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Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.bmg.bund.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/11/15**

Trial Publications, Results and other documents

- Paper **Kramer H, Isensee B, Klapp C, Mais A. Schulische FASD-Prävention im Vorfeld von Schwangerschaften. Eine randomisiert kontrollierte Studie zu den ÄGGF-FASD-Präventionsveranstaltungen in Schulen. gynäkologische praxis 2020; 46: 25-40**

* 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.