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

Trial Description

Title

Recording of psychological distress in the context of occupational medicine screenings after occupational exposure to carcinogenic substances - Possible influence of a modified invitation letter

Trial Acronym

[---]*

URL of the trial

http://-

Brief Summary in Lay Language

The aim of this study is to check, whether a participation in occupational medicine screenings after occupational exposure to carcinogenic substances is related to psychological distress and worries. Therefore, two groups were built: one group received a regular invitation letter for the screening, the other group received a modified invitation letter that included information concerning the background and process of the medical examination. When the invited people attend the screening at the occupational medicine ambulance (Martin-Luther-Universität Halle-Wittenberg), they are asked per questionnaire about their psychological well-being and their health status. The collected data will be analysed concerning possible differences in state anxiety between the two groups.

Brief Summary in Scientific Language

The given study is a randomised clinical trial that takes place at the occupational medicine ambulance of the Martin-Luther-University Halle. We plan to examine people with a former occupational exposure to carcinogenic substances, who are invited to take part in the voluntary examination after being exposed to the substances. The aim of the regular medical examination is to recognise possible changes in health status due to the carcinogenic exposure as early as possible. From our daily work, we gained the impression that many of the participants of the screening are afraid regarding critical results of the examination. The regular letter inviting the people to the screening is quite rational and does not pay attention to the background of the medical examination or possible anxiety-inducing components of the screening. The aim of the study is to find out, whether the occupational medicine screening leads to psychological distress and whether a possible distress can be influenced by modifying the invitation letter. Therefore, we modified the invitation letter and included information on the background and the process of the screening. This intervention should prevent worries due to the screening and reduce the possible psychological distress of the participants. 50 percent of the people will get the modified invitation letter. The regular invitation letter will be sent to the other half (randomized process). Every participant receives a number (ID). Before the regular medical examination starts, three

questionnaires are handed out to the study participants. To analyse the amount of the psychological distress, we use Spielberger's State-Trait-Anxiety Inventory and the SF-12. Furthermore, information about the health status and the smoking behavior will be collected. The study is two-armed and single-blind. The aim is to analyse whether the participation in the occupational medicine screening leads to a certain amount of psychological distress (state-anxiety) and whether the study population differs from the reference population. Additionally, the two groups (control and intervention group) will be compared regarding the state anxiety and the participation rate.

Organizational Data

- DRKS-ID: **DRKS00009221**
- Date of Registration in DRKS: **2016/01/12**
- 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.: **2015-21 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F43.0 - Acute stress reaction**

Interventions/Observational Groups

- Arm 1: **control group: receives regular invitation letter**
- Arm 2: **interventional group: receives modified invitation letter (empathic style, includes Information about the background and the process of the examination, possible worries)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **investigator/therapist**

- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary outcome is the amount of the state anxiety (State-Trait-Anxiety Inventory). A difference of 5 score-points between the groups was selected.

Secondary Outcome

The secondary outcome is the participation rate (occupational medicine screening).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Sektion Arbeitsmedizin, Medizinische Fakultät MLU, Halle Saale**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/05/02**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

former occupational exposure to carcinogenic substances; invitation to take part in the occupational medicine screening (occupational medicine ambulancy, Martin-Luther-Universität Halle-Wittenberg)

Exclusion criteria

refusal to take part in the study; lack of ability to answer the questionnaires independently

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/11/01**

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.*