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

Trial Description

Title

The German Study on Tobacco Use

Trial Acronym

DEBRA

URL of the trial

[---]*

Brief Summary in Lay Language

Approximately one third of the German adult population smokes tobacco. Timely and frequent tracking of national patterns of tobacco smoking and data on the "real-world" effectiveness of smoking cessation methods are needed to inform policies and develop campaigns aimed at reducing tobacco-related harm. In England, the Smoking Toolkit Study (www.smokinginengland.info) has been successfully tracking such key performance indicators since 2006, resulting in the implementation and adaptations of tobacco control policies which have been associated with reductions in tobacco consumption. However, findings cannot be directly transferred into the German health policy context. The DEBRA study aims to provide such nationally representative data.

The DEBRA study begun in June 2016 and consists of computer-assisted, household interviews in people over 14 years. Over a period of at least 3 years, every two months, a new sample of approximately 2,000 respondents will complete the survey (18 waves = approximately 36,000 respondents). Per wave, about 500-600 people are expected to smoke tobacco daily or occasionally or to be recent ex-smokers (<12 months since quitting tobacco). At baseline and six months later, this group will answer detailed questions about rates, duration and success of quit attempts, triggers of quit attempts, exposure to health professionals' advice on quitting, and use of behavioural (medical counselling, group therapy) and pharmacological (nictoine replacement, drugs) cessation aids, including electronic cigarettes.

The DEBRA study will be able to track key variables relating to patterns and trends of smoking and quitting in Germany and will provide information for tobacco control, cessation strategies, and future scientific studies. The methodology of the study is closely aligned to the Smoking Toolkit Study, which will allow international comparisons of data.

Brief Summary in Scientific Language

The prevalence of tobacco smoking in Germany is high (30%). Timely and frequent tracking of national patterns of tobacco smoking and data on the "real-world"

effectiveness of smoking cessation methods are needed to inform policies and develop campaigns aimed at reducing tobacco-related harm. In England, the Smoking Toolkit Study has been successfully tracking such key performance indicators since 2006, resulting in the implementation and adaptations of tobacco control policies, which have been associated with reductions in smoking prevalence. However, findings cannot be directly transferred into the German health policy context. The DEBRA study aims to provide such nationally representative data.

The DEBRA study begun in June 2016 and consists of cross-sectional, computer-assisted household interviews in People over 14 years. Over a period of at least 3 years, every two months, a new sample of approximately 2,000 respondents will complete the survey (18 waves = approximately 36,000 respondents). Per wave, about 500-600 people are expected to smoke tobacco daily or occasionally or to be recent ex-smokers (<12 months). At baseline and six months later, this group will answer detailed questions about rates, duration and success of quit attempts, internal and external triggers of quit attempts, exposure to health professionals' advice on quitting, and use of behavioural and pharmacological cessation aids, including electronic cigarettes. Variables will be analysed considering potential confounders (e.g., strength of urges to smoke and sociodemographic characteristics).

The DEBRA study will be able to track key variables relating to patterns and trends of smoking and quitting in Germany and will provide information for tobacco control, cessation strategies, and future scientific studies. The methodology of the study is closely aligned to the Smoking Toolkit Study, which will allow international comparisons of data.

Organizational Data

- DRKS-ID: **DRKS00011322**
- Date of Registration in DRKS: **2016/11/25**
- 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.: **5386R , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

Health condition or Problem studied

- ICD10: **F17.2 - Mental and behavioural disorders due to use of tobacco; Dependence syndrome**
- Free text: **Smoking behaviour**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Non-smokers:
  Computer-assisted household interviews in people over 14 years. Over a period of at least 3 years, every two months, a new sample of approximately 2,000 respondents will complete the survey.
  Smokers and recent ex-smokers:
  Computer-assisted household interviews in people over 14 years. Over a period of at least 3 years, every two months, a new sample of approximately 2,000 respondents will complete the survey (18 waves = approximately 36,000 respondents). Per wave, about 500-600 people are expected to smoke tobacco daily or occasionally or to be recent ex-smokers (<12 months). At baseline and six months later, this group will answer detailed questions about rates, duration and success of quit attempts, internal and external triggers of quit attempts, exposure to health professionals' advice on quitting, and use of behavioural and pharmacological cessation aids, including electronic cigarettes.
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Characteristics

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

Primary Outcome

Primary aim of the DEBRA study is to track key variables relating to patterns and trends of smoking and quitting in Germany and to provide such nationally representative data to inform tobaccco control, cessation strategies, and future scientific studies. Data will be collected via computer-assisted household interviews at baseline. Smokers and recent ex-smokers will be followed-up 6 months later.

Secondary Outcome

Secondary aim is to compare our primary endpoints with comparable data from other international surveys, particularly from England.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutschlandweit**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/06/15**
- Target Sample Size: **36000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Informed consent

Exclusion criteria

barriers in language, moderate-severe cognitive impairment

Addresses

- **Primary Sponsor**

  Medical Faculty of the Heinrich-Heine-University Duesseldorf
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  40225 Düsseldorf
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  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.uniklinik-duesseldorf.de**
- **Contact for Scientific Queries**

Contact for Scientific Queries

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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.)**

Ministry for Innovation, Science and Research of the German Federal State of North Rhine-Westphalia Germany
Völklinger Str. 49
40221 Duesseldorf
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

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.*