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BMC Public Health

Study protocol of the German Study on Tobacco Use (DEBRA): a national household survey of smoking behaviour and cessation --Manuscript Draft--

Manuscript Number:	PUBH-D-17-00885R1	
Full Title:	Study protocol of the German Study on Tobacco Use (DEBRA): a national household survey of smoking behaviour and cessation	
Article Type:	Study protocol	
Section/Category:	Health behaviour, health promotion and society	
Funding Information:	Ministry for Innovation, Science and Research of the German Federal State of North Rhine-Westphalia	Prof. Daniel Kotz
Abstract:	<p>Background The prevalence of tobacco smoking in Germany is high (~27%). Monitoring of national patterns of smoking behaviour and data on the "real-world" effectiveness of cessation methods are needed to inform policies and develop campaigns aimed at reducing tobacco-related harm. In England, the Smoking Toolkit Study (STS) has been tracking such indicators since 2006, resulting in the adaptation of tobacco control policies. However, findings cannot be directly transferred into the German health policy context. The German Study on Tobacco Use (DEBRA: "Deutsche Befragung zum Rauchverhalten") aims to provide such nationally representative data.</p> <p>Methods/Study design In June 2016, the study started collecting data from computer-assisted, face-to-face household interviews in people aged 14 years and older. Over a period of 3 years, a total of ~36,000 respondents will complete the survey with a new sample of ~2,000 respondents every 2 months (=18 waves). This sample will report data on demographics and the use of tobacco and electronic (e-)cigarettes. Per wave, about 500-600 people are expected to be current or recent ex-smokers (<12 months since quitting). This sample will answer detailed questions about smoking behaviour, quit attempts, exposure to health professionals' advice on quitting, and use of cessation aids. Six-month follow-up data will be collected by telephone.</p> <p>Discussion The DEBRA study will be an important source of data for tobacco control policies, health strategies, and future research. The methodology is closely aligned to the STS, which will allow comparisons with data from England, a country with one of the lowest smoking prevalence rates in Europe (18%).</p> <p>Trial registration This study has been registered at the German Clinical Trials Register (DRKS00011322) on 25th November 2016.</p>	
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Response to Reviewers:	<p>Dear Christina Meier</p> <p>Thank you for the detailed comments on our submission and for giving us the opportunity to submit our revised manuscript entitled "Study protocol of the German Study on Tobacco Use (DEBRA): a national household survey of smoking behaviour and cessation".</p> <p>We have revised the manuscript thoroughly. Please find below our reply to the Editor's comments:</p> <ol style="list-style-type: none"> 1. Ethical and Funding Approval Documentation <ul style="list-style-type: none"> - Please note that this study protocol has been peer-reviewed and approved by the Ethics Committee at the Heinrich-Heine-University Duesseldorf, Germany (ID 5386/R). We have forwarded a copy of the ethical approval (in German) as well as a translated version of the relevant parts to BMCSeriesEditorial@biomedcentral.com. - Daniel Kotz, head of the Addiction and Clinical Epidemiology Research Unit, has been awarded an external grant for this study by a major governmental funding body (Ministry for Innovation, Science and Research of the German Federal State of North Rhine-Westphalia "NRW-Rückkehrprogramm"). This means that the DEBRA study is solely funded by this Ministry of the German Federal State of North Rhine-Westphalia. The study design has been peer-reviewed by members of the funding body. We forwarded a copy of the funding approval (in German) as well as a translated version of the relevant parts to BMCSeriesEditorial@biomedcentral.com. 2. Funding <ul style="list-style-type: none"> Please see our reply to the first comment. 3. Related Articles <ul style="list-style-type: none"> - We certify that no publications containing results of this study have already been published or submitted to any other journal. - We certify that the study protocol has not been published or is being considered for publication elsewhere. 4. STROBE guidelines <ul style="list-style-type: none"> - Not applicable. This manuscript is a study protocol without any results. Reporting of any results of this study in future publications will definitely adhere to the STROBE guidelines for reporting observational research. 5. Remove baseline results <ul style="list-style-type: none"> - We have removed the preliminary baseline results and any reference to them from the manuscript. 6. Move the list of abbreviations to the end of the main text. <ul style="list-style-type: none"> - We have moved the list as suggested. 7. Add a section "Additional files" <ul style="list-style-type: none"> - We have added a new section as suggested to the end of the "Declarations section". 8. Clarify the contributions of author Dennis Nowak

- As described in the manuscript: DK and SK lead the study process, including data collection, data analyses, and the development of new questions for the DEBRA interview guide together with DN. As all listed co-authors, DN contributed substantially to the manuscript.

We hope to have provided all relevant, requested information.

Yours sincerely, on behalf of the co-authors

Sabrina Kastaun

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Study protocol of the German Study on Tobacco Use (DEBRA): a national household survey of smoking behaviour and cessation

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1 **ABSTRACT**

2 **Background**

3 The prevalence of tobacco smoking in Germany is high (~27%). Monitoring of national patterns of
4 smoking behaviour and data on the "real-world" effectiveness of cessation methods are needed to
5 inform policies and develop campaigns aimed at reducing tobacco-related harm. In England, the
6 Smoking Toolkit Study (STS) has been tracking such indicators since 2006, resulting in the adaptation
7 of tobacco control policies. However, findings cannot be directly transferred into the German health
8 policy context. The German Study on Tobacco Use (DEBRA: "Deutsche Befragung zum
9 Rauchverhalten") aims to provide such nationally representative data.

10

11 **Methods/Study design**

12 In June 2016, the study started collecting data from computer-assisted, face-to-face household
13 interviews in people aged 14 years and older. Over a period of 3 years, a total of ~36,000
14 respondents will complete the survey with a new sample of ~2,000 respondents every 2 months
15 (=18 waves). This sample will report data on demographics and the use of tobacco and electronic (e-
16)cigarettes. Per wave, about 500-600 people are expected to be current or recent ex-smokers (<12
17 months since quitting). This sample will answer detailed questions about smoking behaviour, quit
18 attempts, exposure to health professionals' advice on quitting, and use of cessation aids. Six-month
19 follow-up data will be collected by telephone.

20

21 **Discussion**

22 The DEBRA study will be an important source of data for tobacco control policies, health strategies,
23 and future research. The methodology is closely aligned to the STS, which will allow comparisons
24 with data from England, a country with one of the lowest smoking prevalence rates in Europe (18%).

25

26 **Trial registration**

1 This study has been registered at the German Clinical Trials Register (DRKS00011322) on 25th
2 November 2016.

3

4 **Keywords**

5 German Study on Tobacco Use, Epidemiology, Tobacco smoking, E-Cigarette, Household Survey

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7

8 **BACKGROUND**

9

10 In Germany, 110,000 people die from smoking tobacco each year [1]. In total, 13% of the country's
11 mortality is attributable to smoking [1]. While the implementation of various tobacco control
12 policies has led to a reduction in smoking prevalence in high-income countries such as in England
13 (current prevalence = 18%) [2], the prevalence in the German adult population is still high (27%) [3].
14 Like in other countries, smoking prevalence is considerably higher in low income smokers [4, 5],
15 which results in substantial health inequalities between higher- and lower- income groups [6].

16

17 Monitoring of national patterns of smoking and quitting behaviour is needed to inform policies and
18 develop successful campaigns aimed at reducing tobacco-related harm. Relevant parameters to
19 monitor include: smoking prevalence; rates, duration, trigger and success of quit attempts; exposure
20 to health professionals' advice on quitting; the use of harm reduction strategies such as "cutting
21 down"; and the use of cessation aids [7]. Demographic information such as gender or socioeconomic
22 status (SES) and the influence of potential confounders on the smoking cessation process, e.g., the
23 motivation to stop or the degree of nicotine dependence, also have to be considered [7].

24

25 Several national large-scale surveys (ongoing or already completed) [4, 8-10] have been providing
26 useful data on tobacco consumption and smoking behaviour in Germany, but they all have

1 limitations. First, these surveys cover a wide range of addictions and other health topics in general
2 which means that they do not allow for in-depth analysis of data on smoking behaviour. Second,
3 these surveys collect data only on an annual or even less frequent basis. Data are therefore often
4 out of date, and there is a lack of flexibility to adjust survey items to new, specific trends in smoking
5 behaviour (e.g., the introduction of electronic (e-)cigarettes). This limits their topical relevance for
6 tobacco control policies and research. Third, the sample sizes of some of these surveys are not
7 sufficiently large to allow statistically reliable analyses.

8
9 Collection of observational "real-world" data on the effectiveness of smoking cessation methods is
10 important to supplement randomised controlled trials (RCTs), whose generalisability is somewhat
11 limited because of the participant selection criteria. There is good evidence from RCTs that
12 behavioural support and pharmacological treatment, such as nicotine replacement therapy (NRT),
13 bupropion, or varenicline, improve the success of quit attempts [11-15]. However, analyses on the
14 real-world effectiveness of smoking cessation methods from the observational Smoking Toolkit
15 Study (STS) from England [16] showed, for example, that smokers who buy NRT over the counter to
16 aid their quit attempt have similar odds of success as those who tried to stop unaided [17],
17 indicating the importance of providing cessation medication together with behavioural support. The
18 STS is a large ongoing cross-sectional household survey which provides monthly data as well as six-
19 month follow-up data on smoking and cessation behaviour in the English general population aged 16
20 years and older [16]. Findings from the STS cannot be directly transferred to the German health
21 policy context. Whereas behavioural support and pharmacological smoking cessation treatment, for
22 instance, is offered at no or minimal cost in England, such services do not exist in Germany, and
23 evidence-based treatments are not or only partly reimbursed.

24
25 Moreover, little is known about the real-world effectiveness of e-cigarettes for smoking cessation in
26 the German population. Its popularity and usage has rapidly increased in recent years. In England,

1 for example, the prevalence of "ever-users" (people who used an e-cigarette at least once) in
2 smokers and recent ex-smokers has increased from approximately 2% in 2011 to approximately 25%
3 in 2016 [2]. Data from Germany show a comparable trend [3, 18]. Due to design and variety of
4 flavours, e-cigarettes appear popular among adolescents. Authors have debated whether or not e-
5 cigarettes may facilitate nicotine addiction in this age cohort [19, 20]. Therefore, tracking e-cigarette
6 usage behaviour in adolescents is of particular importance.

8 **Aims**

9 The DEBRA study will fill a crucial gap in the literature by collecting up-to-date and in-depth data on
10 key indicators regarding the patterns and trends of smoking and quitting in the German population,
11 helping to guide policy and clinical practice. The collection of baseline and follow-up data provides
12 the possibility for longitudinal analyses on within-individual trends in relevant parameters. These
13 data can contribute to a better understanding of smoking cessation processes in the general
14 population and the role played by triggers such as motivation or physician advice, sociodemographic
15 factors, and aids to cessation such as NRT, behavioural support, or even non-evidence-based
16 methods, including e-cigarettes. The methodology of DEBRA is closely aligned to the STS, allowing
17 comparisons with relevant data from the English population. The study design allows a flexible
18 adjustment of the scope of the survey to address emerging questions relevant to policy changes,
19 practice or research.

22 **METHODS**

24 **Design and Sample**

25 The DEBRA study started in June 2016 to collect data bi-monthly from computer-assisted face-to-
26 face household interviews of people aged 14+. Over a period of 3 years, every two months, a new

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1 sample of approximately 2,000 respondents will complete the survey (= 18 waves, approximately
2 36,000 respondents in total). Per wave, about 500-600 people are expected to smoke tobacco or to
3 be recent ex-smokers (i.e., have smoked in the past 12 months). It is anticipated that data on
4 approximately 10,000 smokers and recent ex-smokers will be collected during the 3-year period. All
5 smokers and recent ex-smokers who are willing to be re-contacted will be followed-up at 6 months
6 following baseline by telephone to complete a short survey. It is expected that about 120-150 (25%)
7 from each baseline wave will agree to be followed-up, resulting in a total sample size of
8 approximately 2,500 respondents with baseline and follow-up data.

10 The fieldwork is conducted by the market research institute Kantar Health Munich, Germany. The
11 investigation area is the Federal Republic of Germany. The total population of the study covers all
12 German speaking persons aged 14 years or over who live in private households during the survey
13 period. To keep the costs manageable, the baseline survey will use a multi-topic omnibus survey, a
14 regular series of surveys from Kantar Health to which questions can be added. Per wave up to 280
15 trained interviewers will conduct on average 7 interviews each. Questions of the DEBRA study are
16 placed in the middle of the 1 hour multi-topic omnibus survey.

18 Baseline data collection will be facilitated through multi-stage, multi-stratified random probability
19 sampling. Firstly, all communities within Germany will be stratified by the following regional
20 attributes: federal state (n = 16), administrative districts (a maximum of n = 41 per federal state),
21 and type of community (a maximum of n = 10 per district). For stratification purposes, these
22 attributes will be used in combination. Hence, each type of community in every administrative
23 district builds a different stratum, which theoretically leads to a total of 410, in practice fewer,
24 strata.

1 To determine the primary sampling units for the study, the geographical area of Germany was
2 divided into 53,000 small areas of approximately equal size, based on communities, and using
3 geographic street mapping system software. For each small area, the sample size was determined in
4 proportion to the total number of households in the area, relative to the total number of households
5 in the whole population. This is called an area sample or sample point. In the current study the
6 number of sample points varies between 360 and 410. All small areas were also allocated to their
7 superordinate geographical units, such as rural and urban districts and municipalities, to allow
8 further stratification of the sample. Sampling units of the second stage will be represented through
9 private households and selected by a random walk procedure. Sampling units of the third stage will
10 be the target persons themselves. These will be selected using a random process (so called
11 "Schwedenschlüssel"), which gives an equal chance of selection to every eligible person within a
12 household [21].

14 **Weighting techniques**

15 Data analyses will take into account weighting adjustments for personal and household
16 characteristics. According to the multi-stage sampling procedure of baseline data the weighting has
17 to be done in separate stages, too. One has to differentiate between the so-called design weighting,
18 which corrects unequal selection probabilities due to the sample design, and the outcome
19 weighting, which corrects disproportions based on the structure of target persons who did or did not
20 participate in the survey. Step 1 and step 3 (see further on) are calculated as rim-weighting within an
21 iterative process. Step 2 is calculated by an analytical approach.

23 *First step (outcome weighting)*

24 The sampling procedure gives every household the same chance to be selected which means that
25 the realised sample should be distributed proportionally to the distribution of private households.
26 Within this first step, the structure of the realised sample is compared to the proportions of the

1 original stratification of the first sampling stage. The weighting factors correct differences between
2 the original and the realised household characteristics.

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7 4 *Second step (design weighting)*

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9 5 In sampling stage 3 (see below) every eligible person within a household has the same chance of
10 selection. Hence, the selection probabilities of the target persons differ across the whole sample
11 according to the size of the household they live in. This unequal selection probability is corrected by
12 an analytical mathematical procedure using the size of the households. The household sample is
13 changed into a sample of persons where every respondent has equal selection probability.

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23 11 *Third step (outcome weighting)*

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26 12 The last weighting step corrects for differences between the demographic structures of the
27 respondents and the structures of the total population using the following structures: Federal states
28 combined with sex and generally seven age classes.

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35 16 **Baseline measures**

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38 17 The main baseline questionnaire for the DEBRA can be found in Additional file 1. To ensure
39 comparability of data, the majority of questions has been adopted from the STS survey and labelled
40 appropriately in the questionnaire [16]. STS questions were developed by an expert panel and policy
41 makers [16]. Existing questions from the STS were translated into German and new questions were
42 developed by a bilingual team of researchers (see authors' contributions) with experience in using
43 the STS data. Some of the validated scales from the STS were translated and culturally adapted
44 according to international guidelines [22].

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57 25 Baseline DEBRA questions for each respondent cover smoking status and ever-use of e-cigarettes.
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59 26 Depending on the response behaviour, current tobacco smokers (cigarettes or other tobacco

1 products), recent ex-smokers (<12 months since quitting tobacco) and ever-users of e-cigarettes or a
2 similar product (e.g., e-hookah, e-cigar, or e-pipe) will answer on further detailed questions about
3 smoking behavior, quit attempts, exposure to health professionals' advice on quitting, and use of
4 cessation aids (Table 1). In addition, socioeconomic data (including age, sex, housing situation,
5 residential area, marital status, education, respondent and household income, and employment
6 status) will be regularly collected in all respondents as part of the omnibus survey.

7
8 The study design is flexible. Depending on trends in population usage of tobacco or nicotine
9 products, in tobacco research, or tobacco control policies, it is intended that new questions can be
10 added from wave to wave while others will be removed when adequate statistical power is reached
11 to address a specific scientific issue.

12 **Six-month follow-up**

13
14 Smokers and recent ex-smokers who agree to be followed-up will be re-contacted by telephone six
15 months following baseline. The computer assisted telephone interviews will be performed by
16 interviewers from Kantar Health's call centre using a Sample Management System (SMS). The SMS
17 manages and controls all telephone contacts (e.g., telephone numbers that cannot be contacted are
18 set deferred, and presented again after a long interval at different times of a day). Interviewers will
19 try to reach the respondents up to ten times at various times and on different days of the week.

20
21 Additional file 2 shows the main follow-up questionnaire for the DEBRA study. Follow-up questions
22 focus on current smoking status and on detailed exploration of any quit attempts that have been
23 made during the past six months. Methods used for a quit attempt (if so) will be asked in
24 concordance to the baseline survey. This prospective element enables us to further analyse the real-
25 world effectiveness of smoking cessation methods using longitudinal data [23] and providing data on
26 within-individual trends. The short time frame between baseline and follow-up takes into

1 consideration the fact that many smokers make multiple quit attempts within a short space of time
2 and often rapidly forget unsuccessful ones [24]. Smokers who try to stop unaided, for example, seem
3 to forget failed quit attempts more quickly than those who use treatment, what might lead to an
4 underestimation of the effectiveness of stop-smoking medications [25].

6 **Main research topics addressed by the DEBRA study**

7 The following research topics will be addressed from the beginning of data collection in wave 1 (June
8 2016). It is very likely that more topics will be added over time.

10 *1. Prevalence rates and monitoring of trends*

11 DEBRA will provide prevalence rates and proportions of key parameters on smoking status, smoking
12 behaviour, quit attempts and their triggers, exposure to health professionals' advice on quitting, and
13 use of evidence-based as well as non-evidence-based cessation aids, including e-cigarettes, stratified
14 by socioeconomic factors, nicotine dependence or motivation to quit. Longitudinal analyses from
15 baseline to follow-up will provide insight into within-individual trends in each of these parameters.
16 Time series analyses will assess changes including seasonal trends, linear trends, and as a function of
17 policy changes or media campaigns.

19 *2. Social gradient in quit attempts and successful abstinence*

20 It is important to determine causes of the higher smoking prevalence rates in disadvantaged groups.
21 Data from the STS showed that smokers in more deprived socioeconomic groups in England are just
22 as likely as those in higher groups to try to stop and use aids to cessation [26]. However, there is a
23 strong gradient across socioeconomic groups in success, with significantly lower success rates in
24 disadvantaged groups being half as likely to succeed compared with the highest [26]. DEBRA data
25 will examine to what extent these findings also apply to different socioeconomic groups in Germany.

1 *3. External validation of the Motivation to Stop Scale (MTSS)*

2 Smoker's motivation to stop smoking is an important source of information, as it predicts the
3 incidence of future quit attempts [27, 28]. Moreover, measuring changes in motivation to stop on a
4 population level is useful to assess and to track the impact of tobacco control policies interventions
5 over time. For this purpose, the single-item MTSS has been developed as a valid and cost-effective
6 tool [27]. The MTSS combines key motivational constructs and has been shown to be a strong and
7 accurate predictor of future quit attempts. With the DEBRA study, we aim to determine the external
8 validity of the translated and culturally adapted MTSS (MRS: "Motivation zum Rauchstopp Skala")
9 among German smokers in predicting future quit attempts.

11 *4. External validation of the Strength of Urges to Smoke Scale (SUTS)*

12 An important criterion for a measure of nicotine dependence is how well it predicts relapse
13 following smoking cessation. A commonly used scale to assess dependence and predict relapse is the
14 Fagerström Test for Cigarette Dependence (FTCD) [29]. However, no representative data have been
15 published on the predictive validity of the FTCD among German smokers. Furthermore, in recent ex-
16 smokers, dependence cannot be measured with the FTCD, as one of its items includes the number of
17 cigarettes smoked per day. By contrast, the two-item SUTS has been found to be a strong indicator
18 of the severity of nicotine dependence and to be a better predictor of relapse than the FTCD [30] in
19 the English population. Its use also allows analyses on the effectiveness of cessation methods (used
20 during the last quit attempt) in recent ex-smokers through adjusting for urges to smoke as a
21 confounder [17]. We aim to determine the external validity of the translated and culturally adapted
22 SUTS (VRS: "Verlangen zu Rauchen Skala") among German smokers and recent ex-smokers in
23 measuring nicotine dependence and predicting relapse.

25 *5. Real-world effectiveness of evidence-based and non-evidence-based smoking cessation methods,*
26 *including e-cigarettes*

1 Numerous analyses on the real-world effectiveness of smoking cessation aids have been conducted
2 with data from the STS in England, for example, to supplement RCT data and to provide estimates
3 for the effectiveness in the general population [17]. However, transferability of STS results to the
4 German health policy context is difficult because evidence-based cessation aids are not or only
5 partly reimbursed in Germany. The DEBRA study will provide such data for Germany. Moreover,
6 hardly any national data is available on usage and real-world effectiveness of non-evidence-based
7 methods, including e-cigarettes. In England, for instance, e-cigarettes have already become the most
8 frequently chosen method of quitting tobacco, possibly contributing to the country's decline in
9 tobacco smoking [31]. The DEBRA study aims at assessing the emerging role of the e-cigarette as an
10 aid in smoking cessation in Germany and evaluating its real-world effectiveness to complement
11 sparse data coming from one existing RCT which found a clinically relevant difference in continuous
12 6-month abstinence between active vs. placebo e-cigarette users trying to quit [32].

13 14 *6. Factors associated with the use of aids to cessation*

15 Recent data from Germany suggest that only a small proportion of smokers use evidence-based aids
16 while trying to quit [33]. Most smokers still try to quit unaided, which is associated with high relapse
17 rates, particularly within the first weeks of abstinence where the strongest withdrawal symptoms
18 occur [34]. The assessment of differences in sociodemographic or smoking characteristics might
19 support health strategies to address specific groups of smokers who are underutilising evidence-
20 based cessation aids in health strategies to a greater extent [35]. Therefore, the DEBRA study aims to
21 analyse variations in use of smoking cessation aids among German smokers trying to quit.

22 23 *7. Exposure to health professionals' advice on quitting*

24 Brief advice on smoking cessation delivered by a physician has been found to be effective and
25 affordable [36, 37]. Hence, clinical practice guidelines recommend implementing brief advice on
26 smoking cessation into routine primary care to assist a large number of smokers. Nevertheless, these

1 recommendations seem to be only rarely implemented into practice in Germany [38] and hardly any
2 representative and up-to-date data is available on frequency of delivery and approaches used to
3 deliver such advice. The DEBRA study aims to provide such nationally representative data to inform
4 policy health strategies aimed at implementing the clinical guidelines.

6 **Data analysis and sample size calculation**

7 Statistical data analyses depend on scientific issues that will be addressed by the DEBRA study.
8 Detailed analyses will therefore be reported in the publication of each future study, respectively.

10 The methodology of DEBRA is closely aligned to the English STS. Our assumptions about expected
11 means and variances for the primary analyses are therefore made on the basis of these STS analyses
12 [17, 23, 39, 40]. Data indicate that, depending on the specific issue, a sample between 1,500 and
13 7,000 interviewed smokers and recent ex-smokers are needed to yield adequate statistical power of
14 >80%. The total required sample size was determined considering current prevalence rates of
15 smokers in Germany [4], available data on rates of cessation attempts within the past 12 months
16 [33], and physician visits within the past 12 months [41], whereas average response rates at follow-
17 up were estimated by Kantar Health on the basis of previous surveys. During the 18 waves of the
18 DEBRA study with approximately 2,000 interviews per wave, about 500-600 people are expected to
19 smoke tobacco or to be recent ex-smokers (in total = ~10,000). Based on these assumptions the
20 required baseline sample sizes from a total of 1,500 to 7,000 smokers and recent ex-smokers can be
21 achieved within 3 years. A response rate of 20-25% is expected at follow-up, resulting in a sample
22 size of approximately 2,500 after 3 years.

24 **Dissemination of findings**

1 Findings from this survey will be reported in national and international peer-reviewed scientific
2 journals, and at national and international conferences. Up-to-date statistics will be also published
3 on the study website: www.debra-study.info.

6 **DISCUSSION**

8 Reducing the prevalence of tobacco smoking is one of the most important strategies for reducing the
9 burden of morbidity, premature death, and health inequalities between higher and lower income
10 groups within the next decades [42]. Continuous monitoring of national patterns of smoking and
11 quitting behaviour as well as real-world data on the effectiveness of smoking cessation methods are
12 needed to guide tobacco control policies and clinical practice.

14 The DEBRA study aims to provide such representative data for Germany. Its methodology is
15 sufficiently flexible to allow adaptations of its research scope and tracking data on every two months
16 permits a much more sensitive test of the possible effects of interventions than can be achieved by
17 annual national surveys. Hence, DEBRA data will provide quick and direct estimates of policy or
18 health strategy impacts aimed at reducing tobacco-related harm as well as of its cost-effectiveness.

20 The results of the DEBRA study can also be relevant to improve clinical care for smokers. Real-world
21 data on the effectiveness of smoking cessation aids might complement the current state of
22 knowledge on evidence-based and non-evidence-based smoking cessation processes which is usually
23 obtained from RCTs. Data on prevalence of the use of such methods and on exposure to health
24 professionals' advice on quitting might help to analyse the as-is state of usage and care. Future
25 interventional studies might then address discrepancies between the as-is (e.g., under-usage of
26 evidence-based treatments to aid cessation) and the target state of use (e.g., use of evidence-based

1 treatments). Such interventions could address both, the physicians and the patients themselves, to
2 increase rates of recommendations as well as the use of evidence-based cessation aids.

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7 4 We expect the DEBRA methodology to be robust and reliable. However, data from the first waves
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9 5 will have to be analysed to compare the representativeness of the DEBRA data to other ongoing
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11 6 national large scale surveys [4, 8-10]. Slight deviations can certainly occur due to different modes of
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13 7 data collection (face-to-face interview, telephone, or online), seasonal fluctuations, differences in
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15 8 weighting procedures, as well as differences due to the inclusion of diverse age groups of
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17 9 participants.
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23 11 There are certain general limitations that apply to large national surveys such as the DEBRA study,
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25 12 including those associated with self-report which may be biased or inaccurate. Furthermore, drop-
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27 13 out rates from baseline to six month follow-up are expected to be substantial and possibly
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29 14 differential. However, representativeness of the follow-up samples will be examined in detail by
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31 15 comparisons with baseline data on key variables from those not followed up and results from such
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33 16 analyses will be interpreted accordingly. Finally, even if the DEBRA study aims to collect a sample of
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35 17 smokers large enough to yield adequate statistical power for several subgroup analyses, certain
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37 18 analyses are likely to be underpowered due to small sample sizes, e.g. in relation to ethnicity,
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39 19 specific professions, or usage of specific e-inhalation products (e.g., e-hookah, e-cigar, or e-pipe).
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47 **Conclusions**

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49 22 The DEBRA study will enhance understanding of factors influencing smoking and cessation behaviour
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51 23 on a population level and be an important resource of scientific data for the development of tobacco
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53 24 control policies, health strategies, and future studies in Germany. The study design allows a flexible
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55 25 adjustment of the scope of the survey to specific trends in smoking behaviour, topical questions in
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1 tobacco research or policies. The methodology of the study is closely aligned to the STS, allowing
2 international comparisons of data.

3

4 **List of abbreviations**

5 DEBRA = German Study on Tobacco Use ("Deutsche Befragung zum Rauchverhalten")

6 DRKS = German Clinical Trials Register ("Deutsches Register Klinischer Studien")

7 E-cigarettes = electronic cigarettes

8 FTCD = Fagerströmtest Test for Cigarette Dependence

9 MTSS = Motivation to Stop Scale

10 NRT = nicotine replacement therapy

11 RCT = randomised controlled trial

12 SES = socioeconomic status

13 SMS = Sample Management System

14 STS = Smoking Toolkit Study

15 SUTS = Strength of Urges to Smoke Scale

16

17

18 **DECLARATIONS**

19

20 **Ethics approval and consent to participate**

21 The study protocol has been peer-reviewed and approved by the ethics committee of the Heinrich-
22 Heine-University Duesseldorf, Germany (ID 5386/R). The fieldwork is conducted by the market
23 research institute Kantar Health Munich, Germany. The interviewers from Kantar Health make sure
24 that all participants give oral informed consent. This method of consent has been also approved by
25 the ethics committee.

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2 Consent to publish

3 Not applicable.

5 Availability of data and materials

6 Data sharing is not applicable to this article as this is a study protocol.

8 Competing interests

9 SK, LSB and CCB have no conflict of interest to declare. JB has received unrestricted research funding
10 from Pfizer, who manufacture smoking cessation medications. LS has received honoraria for talks, an
11 unrestricted research grant and travel expenses to attend meetings and workshops from Pfizer, and
12 has acted as paid reviewer for grant awarding bodies and as a paid consultant for health care
13 companies. RW has undertaken research and consultancy for companies that develop and
14 manufacture smoking cessation medications (Pfizer, Johnsons & Johnson, and Glaxo Smith Kline). He
15 is an advisor to the UK's National Centre for Smoking Cessation and Training. His salary is funded by
16 Cancer Research UK. DN is a member of the advisory board of Pfizer and has received travel grants
17 and honorarium. TR has received honoraria from Pfizer, Novartis, Glaxo Smith Kline, Astra Zeneca
18 and Roche as a speaker in activities related to continuing medical education. He has also received
19 financial support for investigator-initiated trials from Pfizer and Johnson & Johnson. DK received an
20 unrestricted grant from Pfizer in 2009 for an investigator-initiated trial on the effectiveness of
21 practice nurse counselling and varenicline for smoking cessation in primary care (Dutch Trial Register
22 NTR3067).

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26 State of North Rhine-Westphalia ("NRW-Rückkehrprogramm") who had no involvement in the

1 design of the study, the collection, analysis, and interpretation of data, or in the writing of the
2 manuscript.

3

4 **Authors' contributions**

5 DK acquired funding for the current study. DK and SK lead the study processes including data
6 collection, data analyses, and the development of new questions for the DEBRA interview guide
7 together with DN. SK and DK developed and co-wrote the study protocol. The team from the English
8 Smoking Toolkit Study (STS) RW, JB, LSB, ER, TR and LS developed the study design of the STS to
9 which the design of the DEBRA study is closely aligned. LSB, ER, TR, DK and LS were part of the
10 bilingual team which translated the STS questionnaire into German. CCB holds a major part in
11 describing the methodological aspects of the data collection conducted by Kantar Health. All named
12 authors contributed substantially to the manuscript and agreed on its final version.

13

14 **Acknowledgements**

15 We would like to thank Reiner Hanewinkel for his feedback on the early drafts of the baseline
16 questionnaire.

17

18 **Additional files**

19 Additional file 1: DEBRA - Baseline survey (.docx 67 kb).

20 Additional file 2: DEBRA - Follow-up survey.docx (.docx 38 kb)

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1 **Table 1.** Content of the baseline questionnaire for current smokers, recent ex-smokers, and e-
 2 cigarette users

Current smokers and recent ex-smokers	1. Current smoking behaviour (or past smoking behaviour in those that have recently stopped)
	2. Current motivation to quit smoking using the Motivation to Stop Scale [27]
	3. Use of nicotine replacement therapy while smoking
	4. Current (or past) nicotine dependence using the Fagerström Test for Cigarette Dependence [29]
	5. Exposure to health professionals' advice on quitting
	6. Current (or past) strength of urges to smoke [30]
	7. The number of serious quit attempts recalled as having been made within the past 12 months
	8. For the most recent quit attempt within the past 12 months: a. how long-ago the quit attempt started b. how long it lasted c. any aids used (e.g., nicotine replacement therapy over-the-counter, telephone helpline) d. what triggered it (external and internal triggers) e. whether it involved cutting down gradually f. and whether it was planned in advance [7]
E-cigarette users	1. Usage behaviour and its development
	2. Starting age and reasons for e-cigarette use
	3. Type, place of purchase and average consumption of liquid and nicotine in e-cigarettes

3

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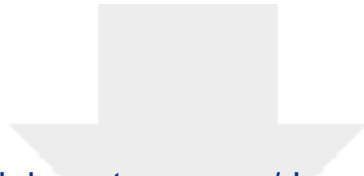
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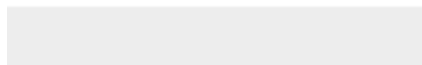
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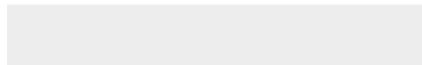


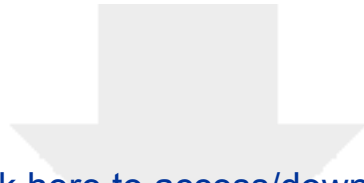


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