🔹Thieme

STudy on E-Cigarettes and Pregnancy (STEP) – Study Protocol of a Mixed Methods Study on Risk Perception of E-Cigarette Use During Pregnancy and Sample Description

Studie zu E-Zigaretten und Schwangerschaft (STEP) – Studienprotokoll einer Mixed-Methods-Studie zur Risikowahrnehmung der E-Zigarettennutzung in der Schwangerschaft und Stichprobenbeschreibung

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ABSTRACT

Introduction During pregnancy, the mother's healthy lifestyle is crucial for the health of the fetus. Potential risk factors for maternal and child health should therefore be identified and reduced as early as possible. The consumption of e-cigarettes represents one of these potential risk factors. Exploring risk perceptions about e-cigarette use during pregnancy can provide early indications of possible user motives. Therefore, our mixed methods **ST**udy on **E**-cigarettes and **P**regnancy (STEP) aimed to comprehensively analyze risk perceptions about e-cigarette use during pregnancy based on an **I**ntegrated **H**ealth **B**elief **M**odel (IHBM). This paper describes the study design, methods, sample population and limitations of STEP.

Methods Our sequential mixed methods study combined qualitative and quantitative approaches. In the qualitative section of the study which preceded the quantitative part of the study, we aimed to characterize risk perceptions about e-cigarette use during pregnancy. We used a netnographic research approach which analyzed discussion threads in online forums dealing with e-cigarette use during pregnancy. The analysis was based on an IHBM. Identified themes were incorporated in the questionnaire which was developed for the quantitative part of the study. The quantitative section aimed to quantify, among other things, perceived threats, barriers and benefits and to explore differences in risk perception according to sociodemographic characteristics and tobacco and e-cigarette usage.

Results In the qualitative section, 1552 posts in 25 online discussion threads dealing, inter alia, with e-cigarette use during pregnancy were identified. The quantitative part looked at the responses in the questionnaires handed in by 575 pregnant women who attended a hospital in Hamburg (Germany) from April 2018 to January 2019 (response rate: 27.5%).

Conclusion Data collection was successful for both the qualitative and quantitative parts of the study. When interpreting the results of STEP, different limitations should be taken into account. The results of STEP provide starting points for the development of tailored preventive measures for pregnant women.

ZUSAMMENFASSUNG

Einleitung Während der Schwangerschaft ist ein gesunder Lebensstil der Mutter entscheidend für die Gesundheit des Fetus. Potenzielle Risikofaktoren für die Gesundheit von Mutter und Kind sollten daher frühestmöglich identifiziert und reduziert werden. Die Nutzung von E-Zigaretten stellt einen dieser potenziellen Risikofaktoren dar. Die Erforschung der Risikowahrnehmung der E-Zigarettennutzung in der Schwangerschaft kann frühzeitige Hinweise zu möglichen Nutzungsmotiven liefern. Unsere Mixed-Methods-Studie zu E-Zigaretten und Schwangerschaft (STEP) zielte daher auf die umfassende Analyse der Risikowahrnehmung der E-Zigarette in der Schwangerschaft basierend auf einem Integrierten Health Belief Model (IHBM). Das vorliegende Manuskript zielt auf die Beschreibung des Studiendesigns, der Methodik, der Stichprobe und der Limitationen von STEP.

Methoden Unsere sequenzielle Mixed-Methods-Studie kombinierte qualitative und quantitative Ansätze. Innerhalb des qualitativen Studienteils, welcher dem quantitativen Studienteil vorausging, zielten wir auf die Charakterisierung der Risikowahrnehmung der E-Zigarettennutzung in der Schwangerschaft. Basierend auf einem netnografischen Forschungsansatz analysierten wir Diskussionsstränge in Onlineforen, die sich mit der E-Zigarettennutzung in der Schwangerschaft beschäftigen. Die Analyse erfolgte in Anlehnung an das IHBM. Die identifizierten Themen dienten der Fragebogenentwicklung für den quantitativen Studienteil. Der quantitative Studienteil zielte auf die Quantifizierung der u. a. wahrgenommenen Risiken, Barrieren und Vorteile sowie der Untersuchung der Unterschiede in der Risikowahrnehmung abhängig von soziodemografischen Eigenschaften und dem Nutzungsverhalten von Tabak- und E-Zigaretten.

Ergebnisse Im qualitativen Studienteil wurden 1552 Beiträge in 25 Onlinediskussionssträngen, die sich u. a. mit der E-Zigarettennutzung in der Schwangerschaft beschäftigen, identifiziert. Im quantitativen Studienteil beantworteten insgesamt 575 Schwangere in einem Krankenhaus in Hamburg (Deutschland) den Fragebogen (Response: 27,5 %) von April 2018 bis Januar 2019.

Schlussfolgerung Die Datensammlung im qualitativen und quantitativen Studienteil verlief erfolgreich. Bei der Interpretation der Ergebnisse von STEP müssen unterschiedliche Limitationen berücksichtigt werden. Die Ergebnisse von STEP liefern Ansatzpunkte für die Entwicklung von gezielten Präventionsmaßnahmen für Schwangere.

Abbreviations

HBM   Health Belief Model
IHBM   Integrated Health Belief Model
TPB   Theory of Planned Behavior

Introduction

In Germany and all over the world, the popularity of electronic cigarettes (e-cigarettes) is increasing. One in five Germans has tried an e-cigarette at least once [1]. E-cigarettes are particularly popular among young adults [1]. Around 3 % of the German population aged 18 to 35 years use e-cigarettes every day [2]. To date, it is unclear how many pregnant women in Germany use e-cigarettes. Recent international research studies estimated the prevalence to be between 0.5 and 15 % [3 – 5].

Using e-cigarettes during pregnancy constitutes a risk factor for the health of the fetus [6 – 8]. Previous animal studies suggest that e-cigarette exposure in utero is associated with epigenetic/organic [9 – 11], pulmonary [9,12] and neurologic/behavioral [13,14] risks for the fetus as well as potentially leading to negative birth outcomes [9]. In particular, the nicotine in e-cigarettes is discussed as a harmful substance. Nicotine is assessed as a toxic substance and associated with multiple negative health outcomes for the fetus [15]. In addition to nicotine, e-cigarettes, even nicotine-free ones, can contain carcinogenic and mutagenic substances, toxic heavy metals, and harmful chemical substances [16,17]. These ingredients may lead to further health risks [16]. Although human studies on the health risks of e-cigarette use during pregnancy are still largely lacking, e-cigarettes cannot be classified as harmless for the fetus. The World Health Organization (WHO) warns against e-cigarette use during pregnancy [18].

In order to obtain adequate information and develop interventional strategies for prevention, it is essential to understand and explore the risk perceptions and health beliefs about e-cigarette use among pregnant women [8,19]. Theoretical models (e.g. Health Belief Model [HBM] [20], Theory of Planned Behavior [TPB] [21]) show that risk perception and its underlying constructs such as perceived threats, attitudes and perceived norms determine decisions about healthy or pathogenic behaviors. Therefore, understanding these perceptions is essential for developing targeted risk communications [20 – 22]. Comprehensive and complex research studies exploring risk perceptions and health beliefs about e-cigarette use during pregnancy based on commonly used behavior models are lacking. Previously published qualitative and quantitative studies have only researched individual aspects of risk perception [3,19,23,24]. To investigate the perception of threats, a few quantitative studies have examined whether pregnant women (or women of childbearing age) perceived e-cigarette use to be harmful for the unborn child or the pregnant woman in general and whether e-cigarette use could lead to lung cancer [3,4,25,26]. Initial quantitative studies have examined potential health and non-health-related reasons or benefits (e.g. e-cigarettes as an aid to quit smoking tobacco cigarettes) of e-cigarette use among pregnant women [3,4,24 – 26]. Existing qualitative studies have only partially examined other

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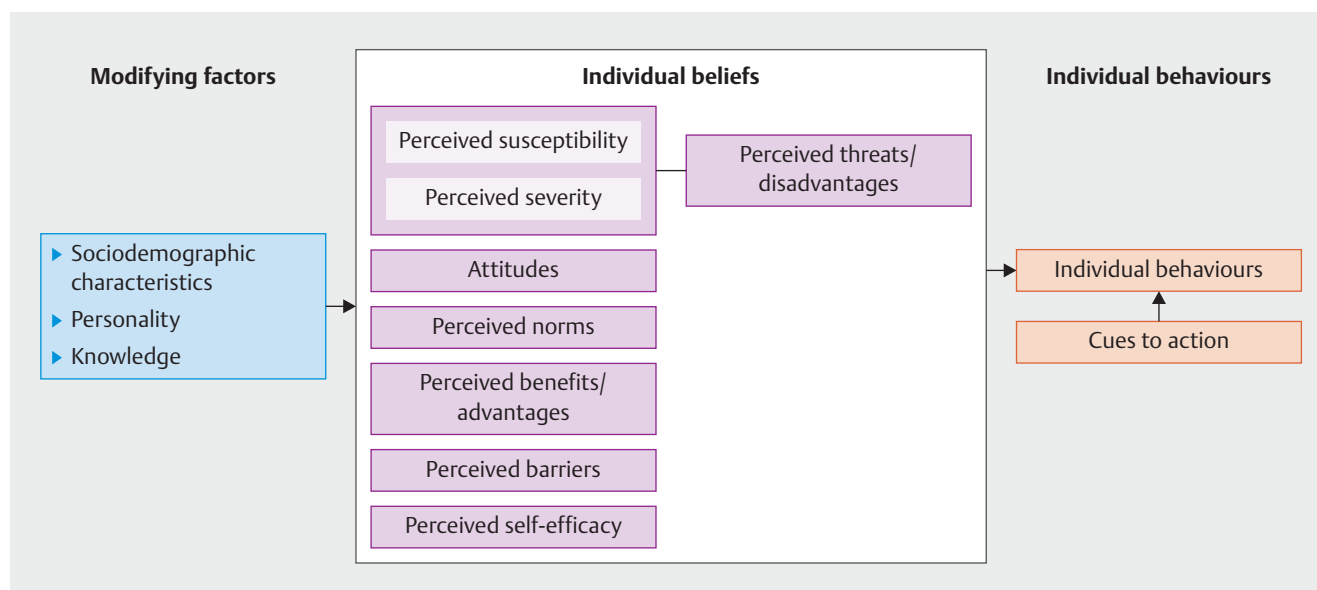
▶ **Fig. 1** Integrated Health Belief Model [22].

underlying constructs of risk perception (e.g. perceived barriers or perceived norms) with reference to e-cigarette use during pregnancy [23, 27, 28].

Even though previous studies have considered a number of individual aspects of risk perceptions about e-cigarette use in pregnancy, little is known about the perceptions regarding potential specific pregnancy-related risks, especially the risks to the unborn child (e.g. the potential harm to the brain and lungs). Moreover, the majority of quantitative research studies on the benefits of and reasons for e-cigarette use during pregnancy only focused on individual benefits. In addition, reported perceptions of benefits of or reasons for e-cigarette use during pregnancy were obtained from studies in the general population and did not consider aspects that are specific to the target group of this study [3]. Finally, little is known about how risk perceptions about e-cigarette use during pregnancy differ according to sociodemographic characteristics and the knowledge about e-cigarette or tobacco usage before or during pregnancy, all of which are important aspects when planning future preventive measures and research studies.

Our **ST**udy on **E**-cigarettes and **P**regnancy (STEP) addresses the knowledge gaps related to risk perception and health beliefs about e-cigarette use during pregnancy. The protocol of the present study describes the research questions, study design, methods, sample population and limitations of our STEP.

Research questions and methodological approach of STEP

The guiding theoretical framework of STEP was an Integrated Health Belief Model (IHBM), which combines elements of the commonly used HBM and the TPB [22] (▶ **Fig. 1**). According to the IHBM, health beliefs and risk perceptions include perceived threats (perceived risks of performing the behavior), perceived barriers (perceived difficulties of performing the behavior), and perceived benefits (perceived advantages of the behavior), attitudes, per-

ceived norms as well as perceived self-efficacy (belief in one's ability to perform the behavior). The IHBM used in STEP was adapted from Case et al. [22] and was previously used in the context of examining e-cigarette use among college students. Performing a study that uses the IHBM in the context of pregnancy can provide valuable insights, since the underlying aspects of the constructs may vary from those of the general population [19].

To obtain a holistic picture of risk perceptions and health beliefs, STEP included a sequential mixed methods study with qualitative and quantitative sections. The combination of qualitative and quantitative data looked at risk perceptions about e-cigarette use during pregnancy from different perspectives and provided detailed and in-depth information about various constructs of risk perception.

The qualitative study part of STEP aimed
- to understand and characterize risk perceptions about e-cigarette use during pregnancy based on the IHBM. It also served to identify themes which were then used to develop a quantitative questionnaire.

In the quantitative part, we aimed
- to quantify the identified constructs of risk perceptions about e-cigarette use in pregnancy and
- identify differences within the perceived risks according to theoretically and empirically selected determinants of risk perception.

The main research questions of STEP were:
- What are the threats, barriers and benefits that pregnant women perceive with regard to e-cigarette use during pregnancy, and are there any differences relating to sociodemographic characteristics, knowledge about e-cigarettes, and the individual usage behaviour of tobacco and e-cigarettes?
- Which attitudes and perceived norms associated with e-cigarette use during pregnancy do pregnant women have and are

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there any differences relating to sociodemographic characteristics, knowledge about e-cigarettes, and the individual usage behaviour of tobacco and e-cigarettes?

Finally, STEP included triangulation and comparison of qualitative and quantitative results with the actual knowledge and state of research on risk perception and the health risks of e-cigarette use during pregnancy to identify starting points for the development of targeted educational and preventive measures.

Material and Methods

Qualitative study section of the mixed methods study
Design and method
The qualitative part of STEP used a netnographic approach, which is defined as "a new qualitative research methodology that adapts ethnographic research techniques to study cultures and communities that are emerging through computer-mediated communications" [29]. German-speaking threads in online discussion forums were identified as the setting. The main reason for choosing this innovative method was to obtain more open, real-life perceptions about e-cigarette use during pregnancy than we could have obtained from face-to-face-methods. Online forums provide a virtual and usually anonymous place for exchanges and the telling of stories about problematic subjects. Tobacco and e-cigarette use during pregnancy can be considered a problematic subject as it is often stigmatized [27, 28, 30]. In addition, discussion threads usually do not arise within research projects and exist independently of the researcher. Thus, they are part of social digital reality [31, 32].

A wide range of online forums about different topics where individuals can discuss predefined or self-initiated topics in numerous different subgroups (threads) exists on the internet [31, 33, 34]. The forms of communication provided by online forums are predominantly asynchronous, meaning that individuals can respond to previous posts in threads over a flexible time period.

Data collection
To identify online forums and threads for the qualitative research part, we performed extensive research using the market-leading internet search engine Google. As a first step, we used variations of the German terms for "e-cigarette" or "pregnancy" and "(online) forum" as search terms to identify e-cigarette and pregnancy online forums. In a second step, the internal search function within the identified online forums was used to identify threads and posts dealing with e-cigarette use in pregnancy. In addition, we performed a Google search with different variations of the term "e-cigarette use during pregnancy" to identify further threads in online forums with different thematic backgrounds (e.g. health forums) that dealt with e-cigarette use in pregnancy (▶ **Table 1**).

In order to document and ensure the quality of the data collection process, we used a series of questions to monitor the quality of data obtained from online discussions based on an approach created by Robinson et al. [34 – 36]. They include questions about the place where the data is found and whether the data makes sense compared with data collected by other means.

Data analysis and data quality
We used an inductive-deductive content analysis approach to analyze the data [37]. For this process, we used the six quality criteria of Mayring [38] to ensure the validity and reliability of the data. They include precise documentation, argumentatively constituted interpretation, rule-governed analysis, subject proximity, communicative validity, and triangulation. The process of analysis and references to quality criteria are described below.

All identified discussion threads were fully or partially copied into separate text files. Threads with a high number of posts on irrelevant topics were screened for relevant parts using the keyword search function. These parts then were copied into the text files. The data were imported into a qualitative analysis software (MAXQDA, Version 12.3; VERBI Software GmbH, Berlin, Germany) to facilitate data organization and analysis. Based on a previously developed process model and analysis rules *(rule-governed analysis)*, in the first step we determined the overarching themes based on the IHBM. These were: perceived threats, perceived benefits, perceived barriers, knowledge, attitudes, perceived norms, and perceived self-efficacy. Afterwards, we inductively coded relevant posts within the threads and identified subthemes. Inductively coded data were discussed and continually refined, while two research students assisted in developing a first scheme of the themes and subthemes which took account of the deduced main themes of the IHBM. Following this step, two members of the research team (LS, SB, see Acknowledgments) coded the identified relevant posts independently, based on the developed scheme. Finally, differences in coding were discussed until a consensus was reached and the themes and subthemes were refined further. Throughout this process, we discussed the interpretations with all authors and other selected research experts *(argumentatively constituted interpretations)*. The first author documented the entire research and analysis process *(documentation)*. Finally, we compared the results of our study with previous results *(triangulation)*.

Quantitative study section
Design and selection criteria
The quantitative section of STEP included a cross-sectional survey of pregnant women who attended the Asklepios Klinik Barmbek, a large hospital in Hamburg. Almost 3000 babies are born every year to pregnant women from Hamburg and surrounding areas in this hospital [39].

All pregnant women who registered to give birth at the Asklepios Klinik in Barmbek between April 4th, 2018 and January 11th, 2019 were eligible to participate in the study. Additional inclusion criteria were an age of at least 18 years and the ability to complete a questionnaire in German. Informed consent had to be given before participation. Participation was independent of whether the pregnant woman knew about or used e-cigarettes.

Data collection and administration
Pregnant women who registered to give birth at the hospital were informed about STEP during their registration interviews. These women were provided with a survey package (including an information sheet, privacy policy, a consent form, a questionnaire and a return envelope) by the midwives responsible for the registra-

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▶ **Table 1** Information about identified threads in online discussion forums (qualitative section of STEP).

Thread	Title of the thread[a]	Period of posts[b]	Number of posts[c]	Forum website
	Pregnancy forums			
1	E-cigarette	August 2011	11	www.wunschkinder.net
2	In support of the e-cigarette	September 2011 – December 2011	14	www.baby.gofeminin.de
3	Smoking during pregnancy	September 2012	81	www.mamacommunity.de
4	Bad addiction	October 2012 – December 2012	10	www.babycenter.de
5	Smoking	November 2012	26	www.hallo-eltern.de
6	Can you smoke herbal cigarettes in pregnancy?	July 2012 – March 2015	18	www.mamacommunity.de
7	Smoking	April 2014 – August 2015	323	www.babycenter.de
8	Is someone a smoker?	August 2015 – December 2016	357	www.babycenter.de
9	Stay away from cigarettes!	December 2015 – April 2016	47	www.babycenter.de
10	E-cigarette	April 2016	4	www.babycenter.de
11	Pregnancy – E-cigarette without nicotine during pregnancy?	November 2016	24	www.urbia.de
12	Stop smoking. But how … (NO MEAN DISCUSSIONS)	November 2016 – March 2017	103	www.babycenter.de
13	Smoke-free throughout pregnancy	July 2016 – May 2017	216	www.babycenter.de
14	Smoking during pregnancy	October 2016 – April 2017	181	www.babycenter.de
15	Vaping during pregnancy	April 2017	15	www.babycenter.de
	E-cigarette forums			
16	Vapes and pregnancy	March 2011	10	www.elektrisches-rauchen.com
17	Pregnancy	December 2011	20	www.elektrisches-rauchen.com
18	New beginners	May 2012	9	www.e-zigaretten.info
19	I switched during pregnancy	June 2014	17	www.e-rauchen-forum.de
20	Vaping and pregnancy	March 2017	18	www.dampfer-board.de
	Health or shisha forums			
21	E-cigarette during pregnancy	8 years ago to – 6 years ago	7	www.gutefrage.net
22	E-cigarette during pregnancy	June 2012 – October 2012	9	www.hilferuf.de
23	Pregnant and smoking	February 2012	20	www.shisha-forum.de
24	E-shisha a "healthy" alternative to cigarettes?	4 years ago	5	www.gesundheitsfrage.net
25	Can pregnant women use electronic cigarettes?	3 years ago	7	www.gesundheitsfrage.net

[a] English translations of German titles of discussion threads
[b] Deadline of search: June 30, 2017
[c] Total number of posts within the threads

tion interview. Women who wished to participate gave their written consent and answered the questionnaire during a waiting period (about 15 to 20 minutes). The participants were asked to personally hand in the sealed envelope to the hospital's midwifery office or to the treating doctor in the hospital.

Development of the questionnaire

The standardized questionnaire was developed based on an extensive literature review and the themes identified in the qualitative section of the study. If available, field-tested items and subscales were adapted for the purposes of our research. If no previous work could be identified, we custom-developed items for the questionnaire.

Contents of the questionnaire

Participants completed a six-page questionnaire. Central themes and subthemes of the questionnaire are presented in ▶ **Table 2**. If items were partially or fully adapted from other questionnaires or studies, we cited those within the text.

Perceived threats/health risks

The questionnaire extensively covered the perceived threats associated with nicotine-free and nicotine-containing e-cigarettes for pregnant women and unborn children. The questions covered perceptions about absolute harms as well as about the specific potential health risks to the mother and the unborn child [6, 9, 10, 12 – 14, 40, 41], overall perceived threats/worries about po-

▶ Table 2 Main themes and subthemes in the questionnaire (quantitative section of STEP).

Themes	Subthemes
Perceived threats/ health risks	Perceived health risks for pregnant women
	Perceived health risks for unborn children
	Overall perceived threats/worries about potential health risks
	Perceived relative risks
Perceived barriers	Health-related barriers
	Addiction/cessation-related barriers
	Other barriers
Perceived benefits	Health-related benefits
	Addiction/cessation-related benefits
	Other benefits
Attitudes	Attitudes about use in general
	Attitudes about the use of e-cigarettes as an alternative to tobacco cigarettes
Perceived norms	Attitudes of the woman's partner
	Attitudes of friends
	E-cigarette use of the woman's partner in general and at home
Knowledge	General knowledge about e-cigarettes
	Knowledge about the ingredients
E-cigarette use	Any use of e-cigarettes
	E-cigarette use before pregnancy
	E-cigarette use during pregnancy
Further health and risk behaviors	Tobacco cigarette use before pregnancy
	Tobacco cigarette use during pregnancy
	Tobacco cigarette use of the woman's partner in general and at home
	Alcohol consumption in the year before pregnancy
	Alcohol consumption during pregnancy
	Physical activity during pregnancy
	Nutritional behavior during pregnancy
Sociodemo-graphic character-istics	Age
	Immigrant background
	Educational level
	Employment
	Marital status
	Week of pregnancy
	Number of pregnancies

tential health risks [25, 42], and perceived threats to the pregnant woman and unborn child compared to tobacco cigarettes [3, 42].

Perceived benefits and barriers

In order to understand the potential health-related and non-health-related reasons for using e-cigarettes during pregnancy, the questionnaire investigated the perceived benefits of e-ciga-

rette use in pregnancy [24 – 26, 43]. As perceived barriers are an important counterpart to perceived benefits, we additionally asked about perceived health-related and non-health-related reasons for not using e-cigarettes and about the barriers to the use of e-cigarettes in pregnancy [22].

Attitudes and perceived norms

In the IHBM, attitudes and perceived norms are considered central elements of risk perception and relevant predictors of health behaviors [44]. This was also reflected in the qualitative data. Therefore, we asked participants about their attitudes regarding the use of e-cigarettes in general and the use of e-cigarettes as an alternative to tobacco cigarettes by pregnant women. We also asked how the use of e-cigarettes (and tobacco cigarettes for comparison) in pregnancy is viewed by partners and friends (= perceived norm) [4, 45]. We additionally included questions about the e-cigarette use of the woman's partner in general and at home [46].

Knowledge

The IHBM cites knowledge as a predictor of risk perception. E-cigarettes are a relatively new product, and previous studies as well as the qualitative section in our study showed that not everyone knows about them. We therefore asked participants whether they were aware of e-cigarettes. By adding a short description of the product, we aimed to include those individuals who did not know about e-cigarettes yet. In addition, we investigated whether the participants thought that e-cigarettes might contain nicotine or tobacco.

E-cigarette use

In order to assess risk perception in the context of the status of the e-cigarette user, the questionnaire included questions about the use of e-cigarettes in the year before pregnancy, during the first months of pregnancy and during the remainder of the pregnancy [47]. In addition, we asked participants whether they had ever used e-cigarettes [1, 24].

Further health and risk behaviors

Certain types of unhealthy behavior are often found in combination with other unhealthy behaviors, and risk perception can vary according to the unhealthy behaviors [48]. We therefore asked the participants about other health-related behaviors before or during pregnancy. These included tobacco cigarette use (in the year before pregnancy, in the first three months, during the remainder of the pregnancy, tobacco cigarette use by the woman's partner) [47], alcohol consumption (year before and during pregnancy) [47], physical activity [46] and nutritional behavior [49].

Sociodemographic characteristics

According to the IHBM, health behavior is influenced by sociodemographic characteristics. In addition to general sociodemographic characteristics such as age, immigrant background [50], educational level, employment and marital status, we asked participants about the week of gestation and number of prior pregnancies (including the number of live births or miscarriages, stillbirths and abortions) [46].

Pretest of the questionnaire

The developed questionnaire was pretested and subjected to an expert review to check and improve its quality. We performed a classic pretest with 10 pregnant women outside the clinical context (14 to 40 weeks of gestation, aged 25 to 36 years). All participants filled out the questionnaire and highlighted any parts they considered incomprehensible. A researcher who attended every pretest session (in person or by telephone) noted the time required for the procedure. The participants were additionally instructed to comment on any incomprehensible parts in the questionnaire and to explain preselected items and questions in their own words to check for comprehensibility. Throughout the procedure, the researcher documented the participants' questions and comments. In addition, the questionnaire was reviewed by two female scientists who had been pregnant less than two years previously as well as by the entire team of authors (including one obstetrician, one medical sociologist and two health scientists). All comments were summarized, and the questionnaire was adapted.

Data analysis

After performing a double entry of the questionnaires, plausibility checks, (re-)coding and data processing, a descriptive analysis of the items about risk perception and status of e-cigarette and tobacco cigarette users before and during pregnancy was conducted. In a second step, differences within these factors relating to sociodemographic characteristics (e.g., age, immigrant background, educational level), knowledge about e-cigarettes, other health behaviors (and e-cigarette user status in the context of risk perception) were analyzed using χ^2 test and t-test for paired samples. Based on bivariate analysis, risk perceptions were then examined using multiple regression and cluster analysis in accordance with the IHBM. All quantitative analyses were performed using IBM SPSS Statistics version 22 (IBM, Armonk, USA).

Results

Qualitative section

We were able to identify a total of 25 threads containing 1552 posts in 14 online forums as relevant for our analysis. The search was conducted between April and June 2017. A summary of the relevant information in the identified threads is given in ▶ Table 1.

Quantitative section

During the above-mentioned period between April 4th, 2018, and January 11th, 2019, a total of 2092 pregnant women registered to give birth at our hospital. 575 of these pregnant women completed the questionnaire and were included in the analysis (response rate: 27.5%). The mean age of the study population was 32.20 (SD 4.67) years and the mean week of gestation was 32.26 (2.74) weeks. ▶ Table 3 provides an overview of the characteristics of the study population. Although a full comparison of our study population with the entire group of women who registered at the hospital during the survey period was not possible, we were able to compare our study population with the entire group of women who gave birth in the Asklepios Klinik Barmbek in the sur-

▶ **Table 3** Sociodemographic characteristics of the study participants (quantitative study part of STEP[a]).

Sociodemographic characteristics	Study participants (n = 575) n (%)	Total number of women who gave birth in the selected hospital during the study period (n = 2540) n (%)	χ^2 test
Age			
▪ 18 to 29 years	164 (29.7)	816 (32.1)	
▪ 30 to 35 years	257 (46.5)	1056 (41.6)	p = 0.106
▪ > 35 years	132 (23.9)	668 (26.3)	
Immigrant background			
▪ No	410 (73.9)		
▪ Yes	145 (26.1)		
Level of education			
▪ Low	30 (5.7)		
▪ Moderate	136 (25.9)		
▪ High	359 (68.4)		
Partner			
▪ No	23 (4.2)		
▪ Yes	531 (95.8)		
Children			
▪ No children	326 (57.7)		
▪ 1 child	198 (35.0)		
▪ 2 or more children	41 (7.3)		
Week of gestation			
▪ < 29	49 (8.8)		
▪ 29 to 34	389 (69.5)		
▪ ≥ 35	122 (21.8)		

[a] All reported data obtained from valid cases

vey period using the only available sociodemographic variable "age". We found no significant differences between the two groups with regard to age (▶ Table 3).

Discussion

This study protocol describes the research questions, study design, methods, study population and limitations of STEP. STEP used a sequential mixed methods approach to extensively explore risk perceptions about e-cigarette use during pregnancy. The results of STEP will be published in high-quality scientific and peer-reviewed journals and presented at national and international conferences and will additionally be made available to stakeholders and the general public. The German Cancer Research Center (DKFZ) has committed to presenting the study results to both po-

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litical and non-governmental representatives at annual German conferences for tobacco control.

Strengths and limitations

To our knowledge, STEP is the first study which extensively explores risk perceptions and health beliefs about e-cigarette use using common behavior models. In addition, STEP is the first study to explore the use of e-cigarettes and the risk perceptions about e-cigarette use during pregnancy in Germany. The key strength of the study is its mixed methods design. Nevertheless, the following limitations must be addressed.

Qualitative section

Firstly, the interpretation of the qualitative data is limited because of the lack of information about the sociodemographic characteristics of forum users. Further sociodemographic information might have led to more detailed insights and a better understanding of risk perceptions and health beliefs. Secondly, our results could be selective, as they exclusively considered active forum users and not everyone actively comments in online forums. Thirdly, the discussions and posts about e-cigarette use during pregnancy might be steered by the forum providers. According to the terms of use, forum providers may edit, shorten, or delete posts and threads (e.g. [51, 52]). Since our identified e-cigarette forums are mainly financed by e-cigarette shops or e-cigarette traders (e.g. [52]), the possibility cannot be excluded that posts objecting to e-cigarettes might have been deleted. Because of these aspects, the results of STEP cannot be generalized. Nevertheless, the collection of data from online discussion forums offers advantages over face-to-face methods. Online forums can give a voice to individuals who may otherwise be difficult to reach (e.g., parents of young children) when using more time-consuming research methods such as focus groups [42, 45]. In addition, access to online forums is usually easy and barrier-free [46]. Online forums can provide a platform to discuss stigmatized and taboo topics, such as smoking and vaping during pregnancy [27, 28, 30].

Quantitative section

The representativeness of the study population is limited because of the low response rate of 27.5%. Therefore, our quantitative survey only reflects the perceptions and attitudes of a subset of pregnant women. As our study is the first study to examine the risk perceptions of pregnant women in Germany about e-cigarettes, it reveals important findings. One potential reason for the low response rate could be that participants were only recruited by means of a single personal invitation issued by one midwife. As recommended in previous research studies, response rates can be increased if participants are followed up and a multimodal approach is used (e.g., personal invitation, invitation via e-mail or phone) [53]. Due to the limited temporal and financial resources of the midwives and the research team, a multimodal approach was not feasible.

As described in the Results section, the age structure of our sample did not differ significantly from that of the total group of women who gave birth in the same hospital in Hamburg during the study period. Since we had no further sociodemographic information about the women giving birth during the study period, we additionally compared the level of education of the women in our study population with those of women aged 20 to 40 years living in Hamburg [54]. Compared to the overall group of women from Hamburg, the percentage of women with low levels of education was three percentage points lower in our sample. In Hamburg, 8.5% of women aged 20 to 39 have low levels of education [54]. By comparison, national figures show that 18% of the general population of women aged 20 to 40 years in Germany have low levels of education [55]. Since smoking before and during pregnancy is more likely among women with low levels of education [56], our results – especially with regard to the use of tobacco and e-cigarettes – may even be underestimates. Nevertheless, low participation rates among women with low levels of education are not uncommon in birth cohort studies. Of the women who participated in the BaBi study, 7.8% had low levels of education [57]. In the Ulm SPATZ Health study, 9.7% of the surveyed pregnant women had been educated for 9 years or less [58].

Social desirability may also have affected responses, especially with regard to the use of e-cigarettes or tobacco cigarettes, as well as the attitudes about e-cigarette consumption during pregnancy. To reduce potential social desirability bias in our study, participants were told that none of the medical providers at the Asklepios Klinik Barmbek were authorized to open the sealed envelopes and that they would not be informed about individual answers. In addition, participants were informed that opening and analysis of the questionnaires would take place outside the hospital at a later point in time, involving an independent research team at the Mannheim Institute of Public Health, Social and Preventive Medicine, Mannheim, Germany.

We limited our analysis to cross-sectional data to obtain a snapshot in time of behaviors and perceptions that may change significantly for individuals and across time. Perceptions about e-cigarettes in particular may change rapidly in response to advertising strategies, preventive measures and local tobacco policies. Our quantitative results thus show a single sequence of risk perceptions in 2018/2019.

Conclusion

STEP is the first study which explored risk perceptions about e-cigarette use during pregnancy using standard behavior models. In the present paper we describe the successful data collection and the identified study population for the qualitative and quantitative sections of the study and the study limitations. Future studies about the research questions raised by STEP are planned and will be published in national and international journals. STEP will provide early indications of user patterns and motives. It can thus assist in the development of adapted risk communications and adequate prevention strategies by researchers and medical providers to minimize the risk factor of e-cigarette use as early as possible pregnancy.

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Declarations

Ethical approval and patient consent

The Medical Ethics Committee of the Medical Faculty in Mannheim (Heidelberg University; 2017-505 N-MA) provided the initial study approval which was forwarded for review and approved by the Ethics Committee of the Hamburg Medical Chamber (MC-178/17).

As is common and ethically tenable in research activities about online forums, forum users were not informed about their posts being used for research purposes. The threads were publicly available, and no registration was required to read the threads in the online forums.

As part of the quantitative section of the study, participants received a survey package providing information about the objectives, the procedure, risks, benefits, study contacts and data security. In addition, the participants were assured that participation was voluntary and that non-participation would have no negative consequences and no impact on their further treatment at the hospital. Moreover, the participants had the opportunity to withdraw their consent. Only those participants who gave their consent were included in the study.

Conflict of Interest

The authors declare that they have no conflict of interest.

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