

# BMJ Open What happens when you stop using the combined contraceptive pill? A qualitative study protocol on consequences and supply needs for women who discontinued the combined contraceptive pill in Germany

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## ABSTRACT

**Introduction** For more than 60 years, contraceptive pills have been prescribed to mostly healthy biological women. An emerging body of research concerning the possible physiological and psychological side effects of hormonal contraception has been published over the past two decades. Consequently, discontinuing combined oral contraceptives (COCs) as a conscious decision for reasons other than desired pregnancy has become increasingly common for menstruating individuals. The question remains as to what physical and psychological consequences can be observed after discontinuing COCs. In addition, the consequent healthcare needs and situations of affected individuals in Germany have not been explored. This study aims to gain greater insight into the relationship between discontinuation of COCs and (1) possible health consequences, and (2) to explore the supply situation for affected women within the German healthcare system.

**Methods and analysis** Qualitative episodic interviews with women who discontinue COC therapy will explore possible health consequences, and their current healthcare needs and situations in Germany. The interviews will be transcribed verbatim, coded, and in-depth thematic interpretation will be conducted. Subsequently, expert interviews with health professionals who work with women who discontinue COCs will also be conducted. The expert interviews will be analysed according to the documentary method. Overarching themes will represent the perspectives of women and health professionals on the discontinuation of COCs.

**Ethics and dissemination** Ethical approval for this study has been granted by the Ethics Review Committee of Martin Luther University, Halle-Wittenberg (Germany), reference number 2021-34. The findings will be disseminated via peer-reviewed publications, posting via social media and presentations at conferences. This study is registered on the OSF platform under the following number: <https://doi.org/10.17605/OSF.IO/JYWXM>.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will allow a detailed exploration of the personal experiences of women and will therefore add valuable information to existing clinical/epidemiological research.
- ⇒ The results of this study may provide an important basis for future inductive research on quantitative health.
- ⇒ As the study will be conducted in the context of the German healthcare system, the investigation of the quality of care will be limited.
- ⇒ Due to the small sample size, the data may not be generalisable.

## INTRODUCTION

### Combined oral contraceptives: epidemiology and health consequences

The contraceptive pill is among the most commonly used contraceptive in Europe today; on average, 19.1% of women of reproductive age (15–49) use the pill. The prevalence of contraceptive pill usage is reportedly the highest in Northern and Western Europe (25.6%, 31.5%) and lowest in Eastern and Southern Europe (11.0%, 15.8%).<sup>1</sup> Since their launch in 1960,<sup>2</sup> a total of three new generations of combined oral contraceptives (COCs) have been approved, which differ in their composition of artificial estrogens and progesterones (progestins).<sup>3</sup> According to Khialani *et al*,<sup>4</sup> COCs that contain the progestins levonorgestrel, norethisterone or norgestimate were the most prescribed COCs in Denmark, the Netherlands and the UK. In Germany, 4th generation COCs containing the progestin dienogestare are currently the most prescribed COCs.<sup>5</sup>

The pill was one of the first drugs to be taken up by healthy biological women and can have intentional and unintentional effects.<sup>6</sup> The main desired effect is the prevention of pregnancy caused by a constant intake of artificial hormones.<sup>5</sup>

Unintentional effects differ between generations of COCs.<sup>7</sup> Positive unintended effects can include the treatment of hyperandrogenism,<sup>8</sup> dysmenorrhea<sup>9</sup> and premenstrual syndrome.<sup>8 10–12</sup> Unintended negative effects can be both physiological and psychological. Negative physiological side effects found to be associated with COCs include increased stress hormone profiles<sup>13</sup> and risk of venous thrombosis.<sup>14 15</sup> The intake of 3rd generation COCs was associated with an increased risk of thrombosis of 1.5–2 times more than that of 2nd generation COCs. This figure represents an incidence of 9–12 embolisms per 10 000-person years of treatment.<sup>16</sup> Additionally, the negative psychological effects associated with COC use can increase the risk of depression, suicide attempts and completed suicide.<sup>17 18</sup>

### Critical, feminist views on COCs

‘My body is my own’—since their introduction, COCs and their possible effects have been part of feminist debates.<sup>19–23</sup> On one hand, COCs support the medicalisation of the (biological) female body and the suppression of natural femininity. However, they also challenge gender norms by empowering women to choose when and if they want to become biological parents.<sup>6 19 20 24</sup> When the first contraceptive pill was introduced to the market nearly 60 years ago, women had ‘limited reproductive autonomy’.<sup>25</sup> In our post-feminist society,<sup>25</sup> the pill is no longer only used as a contraceptive. It is marketed to consumers as a lifestyle drug that has desirable contraceptive and non-contraceptive effects.<sup>26</sup> Of course, there are still currently many countries where reproductive autonomy and ready availability of modern contraceptive methods have not yet been achieved.<sup>27–29</sup>

Recent scientific findings on the possible side effects<sup>13 17</sup> of COCs have led to increasing criticism of their use.<sup>7 24 30</sup> This is evident in the scientific literature, which argues that immediate side effects (eg, mood swing, headache),<sup>31–33</sup> or fear of possible side effects and possible health consequences are among the main reasons women give for discontinuing, or choosing not to use, hormonal contraceptive use.<sup>31 34–37</sup>

### The discontinuation—the state of art and required research

Scientific studies addressing this issue have mainly focused on the return of menstruation<sup>38–41</sup> and fertility<sup>39 41 42</sup> or collecting the reasons for discontinuation.<sup>43</sup> However, Inoue *et al*<sup>43</sup> argued that clinical and epidemiological studies do not describe the personal reasons women discontinue contraceptive use. With the growing number of women who stop COCs for reasons other than pregnancy,<sup>31 34 35 44</sup> a new demand for consultation on related health issues might exist. Research also shows that women want more autonomy with regard to contraceptive

choices.<sup>45–48</sup> Therefore, a healthcare supply gap could arise.

Health issues, which might appear after discontinuation of COCs, have recently been described by Brighton as the Post-Birth-Control-Syndrome; ‘a constellation of symptoms women experience, when they discontinue hormonal birth control’.<sup>49</sup> To the best of our knowledge, no scientific studies have observed the nature and frequency of the non-fertility-related symptoms experienced after discontinuation of COCs. Furthermore, there is a paucity of scientific information regarding health service research about women who stop taking COCs, including the possible resulting healthcare gaps for universal healthcare systems, in countries such as in Germany. Inoue *et al*<sup>43</sup> pointed out the need for women to articulate their personal views and reasons for cessation of contraceptive use in their own words.

Owing to the lack of evidence, this qualitative research aims to inductively explore possible health issues and advantages following the discontinuation of COCs, as described above. Exploration will allow the definition of hypotheses which could form the basis for future research designs. The results also represent an important contribution to health service research for women in Germany and other universal high-quality healthcare systems.

### Study objectives

The primary objectives of this study are to first explore the physical and psychological changes women in Germany observe after discontinuing COCs. Second, to explore the supply situation for affected women within the German healthcare system. The secondary objectives are as follows:

1. To understand the practice of discontinuation with regard to COCs and the underlying motives.
2. Identify knowledge bases about potential health consequences after discontinuation of COCs and explanatory influencing factors.

## METHODS AND ANALYSIS

### Study design

This sequential multiperspectival qualitative research project aims to explore the objectives of the study. A mix of qualitative data collection methods and analyses will be used. First, data will be collected through structured episodic interviews with women who have ceased COC use.<sup>50</sup> Second, expert interviews with health professionals will provide a different perspective on the research problem.<sup>51</sup> Key issues and points will be captured in both interview forms. This allows the perspectives and views of the women concerned and health professionals to be contrasted.

### Patient and public involvement

No patients were involved in the design of this study.

## Sample and recruitment procedures

### Participants

In general, interviewees should be willing and motivated to participate in the interview process.

### Episodic interviews

Persons of interest for the first qualitative study are women of reproductive age (18–44 years) in Germany who discontinue COCs. Interviews will be conducted with people who meet the study inclusion criteria: (1) reproductive cis-gender women, aged 18–44 years, (2) who live in Germany, (3) have statutory or private insurance status in Germany and (4) have stopped taking the pill in (5) a period of at least 3, and at most 12, months prior to the start of the interviews. Non-cis-gender women assigned as females at birth will be excluded from this study because they may be taking other hormonal medications. Pregnant women will be eligible for inclusion if there was a period of at least 6 months between discontinuation of COCs and pregnancy.

### Expert interviews

This data collection will include: (1) health professionals who manage women who have stopped COCs (eg, gynaecologists, dermatologists or alternative practitioners) within the German healthcare system; and (2) persons who have dealt with the healthcare situation of women who have stopped COCs and focus on women's health. The definition of an expert may evolve further through the research process and based on episodic interviews. Individuals who do not correspond to this professional profile will be excluded.

### Sample size

To investigate the sample size for both qualitative studies, theoretical sampling will be used.<sup>50 52</sup> Thus, the exact number of participants will be determined based on data saturation. The minimum sample size component of the study will be 10 interviews. Data saturation will be reached if, after three additional interviews, no new phenomena or cases (eg, similarity of experiences with weaning) emerge. In accordance with Francis *et al*,<sup>53</sup> the stopping criterion will be tested after each subsequent interview (ie, 11, 12 and 13 and so on).

### Sampling and recruitment procedure

The research project will be conducted from January 2023 to November 2024.

### Episodic interviews

Purposive/purposeful, quota and snowball sampling will be used to ensure the diversity of the sample in terms of intersectionality (eg, age, socioeconomic status, regional diversity).<sup>52</sup> This also ensures contrast between the interviewees, as well as the generalisability of the study. Recruitment will be carried out mainly through social media (posts on Instagram, Facebook and Twitter) and according to the snowball principle.

### Expert interviews

Again, purposive/purposeful, quota and snowball sampling<sup>52</sup> selection of cases will be used. Experts should reflect the diversity of women's healthcare, including healthcare groups such as gynaecologists, dermatologists and alternative practitioners. Precise information on the targeted experts will be based on the information received from the episodic interviews. For the recruitment of experts, recommendations from the episodic interviews (snowball principle), as well as the scanning of media (eg, podcasts) and the exploration of organisations with a focus on women's health in Germany (eg, 'ArbeitskreisFrauengesundheit in Medizin, Psychotherapie und Gesellschaft e.V.'<sup>54</sup>) will be considered.

### Data collection

Data will be collected using two qualitative methods applied sequentially: (1) episodic interviews and (2) expert interviews.

### Episodic interviews

Guided episodic interviews (according to Flick<sup>50</sup>) with affected persons will be used as the first data collection method for the investigation of the research problem. The interview form was chosen because it allows both narration of the interviewee and targeted questions from the interviewer. In addition, the episodic interview form focuses on experiences that are appropriate for the research topic. Moreover, the episodic interview itself includes a combination of methods and therefore allows triangulation.<sup>50</sup>

Interviews will be conducted face-to-face or via a video conference tool (DFNconf<sup>55</sup>) at the participant's convenience and under consideration of the current developments in the SARS-CoV-2 pandemic. An interview guide will cover topics regarding the use, discontinuation and personal healthcare experiences of women when they cease COC therapy (table 1). Additional probes will be developed by considering the existing literature and a commonly used health behaviour model. An interview protocol will examine the demographic information (eg, age, occupation) and specific questions about the history of COC intake (eg, length of COC intake, type of COC) of the interviewees. The interviews should last for approximately 30–60 min; However, this is likely to vary greatly depending on the personal experiences of the interviewee.

Before data collection, the interview guide will be tested with a minimum of two individuals.

### Expert interviews

According to Meuser and Nagel,<sup>51</sup> expert interviews are used to provide a complementary perspective in a research field. This is intended to achieve broader understanding and greater depth. The contextual (eg, regarding affected women and the topic) and operational (eg, regarding the care situation of affected menstruating persons) knowledge experts may provide is relevant.<sup>51</sup>

**Table 1** Themes of the interview guide for the episodic interviews

Theme	Sample question
The first contact with the pill	Can you perhaps remember your first points of contact with the pill?
The reasons for taking the pill	When you think back: please describe your motivation for taking the contraceptive pill.
The time during pill-taking	Describe the time when you were taking the pill. Can you remember an event that describes it particularly well?
Reasons for stopping the pill	Could you please describe your personal motivation for stopping the pill? Can you perhaps tell me about a situation that describes this particularly well?
The period of discontinuation of the pill	Please describe your experience after you stopped taking the pill. Can you describe a specific situation that characterises it particularly well?
Current contraceptive method	Please describe your current contraceptive situation.
The medical needs and their quality in relation to taking and discontinuing the pill	Please describe to me what health needs you had while taking the pill.
Closing questions	How would you summarise your experience of stopping the pill in one central lesson?

Because the specific questions of the interview guide will be based on the evaluation of the episodic interviews, only the preliminary thematic complexes for the interview have been devised:

- ▶ The pill as a contraceptive.
- ▶ Taking the pill.
- ▶ Discontinuing the pill.
- ▶ The supply situation for contraceptives in general.
- ▶ Final questions.

Further, additional probes will be developed by considering the existing literature and a commonly used health behaviour model. Moreover, expert interviews should provide a contrast to the perceptions of women themselves.

As in the episodic interviews, expert interviews will be conducted face-to-face or via a video conference tool at the participant's convenience and under consideration of the current developments in the SARS-CoV-2 pandemic.

Before data collection, the interview guide will be tested with a minimum of two individuals.

### Data analysis

All interviews will be audio-recorded and transcribed verbatim. Data management and analysis will be performed using MAXQDA software. For quality assurance and the presentation of results, the standards for reporting qualitative research will be considered.<sup>56</sup> A research associate (JN) will code and analyse the collected material. To ensure intersubjective comprehensibility, approximately 25% of the material for both episodic and expert interviews will be coded by another member of the research team. The codes will be compared and discussed until consensus is reached. The kappa coefficient will be reported to increase rigour. In addition, the work will be presented in qualitative research groups at the Institute for Medical Sociology at the Martin-Luther University Halle-Wittenberg and the Medical Sociology and Rehabilitation Science at the Centre for Human and Health Sciences of Charité University Berlin. There will be a

continuous exchange with the head of the project (MR) and professors (LS) and (GS).

The analysis of the episodic interviews will be performed following the process devised by Schmidt.<sup>57</sup> First, categories will be developed based on the transcribed material. For this, open coding will be applied. To guide this process, the research questions and the structure of the guide will be used. This will include a coding scheme with definitions and examples for each code. Subsequently, the interview material will be coded. After coding, the material will be quantified in overview. This shows which cases are particularly typical or deviating in the overall picture. Based on these results, an in-depth case interpretation will be performed. Which should exhaust the abundance of material while providing an exhaustive description of the sample.<sup>57</sup>

For the expert interviews, the evaluation method defined by Meuser and Nagel, which was developed specifically for expert interviews, will be applied.<sup>51</sup> The data analysis will be based on thematically related passages. Coding is to be carried out deductively and inductively. A category system will be developed from the interview guide, thus dividing the material into thematic sections. Subsequently, new categories were inductively added. The coding will be based on theory and on current literature.

### ETHICS AND DISSEMINATION

#### Ethics approval statement

Ethical approval has been granted by the Ethical Review Committee of the Medical Faculty at Martin Luther University Halle-Wittenberg (reference number 2021-034). Recommendations made by the committee for the study have been implemented. The committee did not express any ethical concerns.

## Ethics

This research project will be conducted in accordance with the principles of the Declaration of Helsinki and good scientific practice.

Participants will receive all relevant study information before the interviews are conducted. Informed consent will be obtained from all the interview participants for the study. In addition, information regarding data management will be provided. A written declaration of consent, which follows the data protection requirements of the General Data Protection Regulation, will be provided before the interview. Participation can be discontinued at any time without giving reasons. If this occurs, the data already collected will be irrevocably deleted. Withdrawal has no (legal) consequences for the participants.

Procedures will be implemented to minimise potential harm. Interview data (records and transcripts) will be stored separately from personal data throughout the research project. All participant information will be removed from the interview data by assigning pseudonyms to the identifying data. Personal data will be stored on a password-protected data stick (USB stick) provided for this purpose. This will be stored in a locked cabinet in a room with double-locking authorisation at the university. These procedures will secure the participants' privacy and confidentiality.

## Dissemination

The results of the studies will be published in peer-reviewed academic journals. For this study, an Instagram account will be created (@whats\_happens\_project). Using this Instagram account, published study results and updates will be disseminated. The results will be presented at national and international conferences.

## SIGNIFICANCE AND IMPACT OF THE STUDY

This study can provide valuable insights and information about the healthcare needs of women taking and ceasing to take COCs. The qualitative nature of the study has the advantage that it focuses on the personal reasons and experiences of those affected, and contrasts these with the views of experts. This will be a valuable addition to the existing published biomedical/epidemiological research. Moreover, it provides real-world evidence relevant to health service research with the potential to influence regulatory decision making in health agencies. Finally, this study can contribute to the establishment of a research base on gender health and contraception for future research in Germany and other universal high-quality healthcare systems.

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