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Assessment of person-centeredness in healthcare and social support services for women with unintended pregnancy (CarePreg): protocol of a mixed methods study

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3 1 **Assessment of person-centeredness in healthcare and social support services for women with**
4
5 2 **unintended pregnancy (CarePreg): protocol of a mixed methods study**
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53 27 Issue Date: July 20th 2022
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1 **ABSTRACT**

2 **Introduction**

3 Person-centeredness (PC) incorporates the preferences, needs, and values of the individual concerned
4 in care provision. For women with unintended pregnancy, access to high-quality care has been found
5 limited due to social stigma and legal restrictions, especially when seeking abortion. To foster PC,
6 recognizing the experiences and needs of women is the first premise. Therefore, this study aims to 1)
7 identify relevant dimensions of PC in care for women with unintended pregnancy, 2) evaluate PC in
8 healthcare and social support services from the perspective of women with unintended pregnancy, 3)
9 develop recommendations for further actions in healthcare and social support services.

10 **Methods and analysis**

11 A mixed-methods approach will be used. In phase 1, expert workshops with healthcare professionals
12 and counselors and semi-structured interviews with women with unintended pregnancy will be
13 conducted to assess the relevance of the dimensions of PC. In phase 2, quantitative assessment of
14 dimensions of PC within healthcare and support services will be conducted. We will include women with
15 an unintended pregnancy a) until 24 weeks of pregnancy or b) who sought abortion within the past eight
16 weeks. There will be three measurement points within twelve months. To deepen the results, semi-
17 structured interviews will be conducted. In phase 3, an expert workshop and an online survey will be
18 used to indicate recommendations for healthcare. An ethical advisory board and an advisory board of
19 affected women will be involved throughout the study.

20 **Ethics and dissemination**

21 The study will be carried out in accordance to the latest version of the Helsinki Declaration of the World
22 Medical Association and principles of good scientific practice. The study was approved by the Local
23 Psychological Ethics Committee of the University Medical Center Hamburg-Eppendorf, Germany
24 (LPEK-0260). The study results will be disseminated in scientific journals, through collaboration partners
25 and plain language press releases.

26 **Keywords:** person-centeredness; patients' experiences, unintended pregnancy; abortion care;
27 pregnancy care; mixed methods; patient-reported experience measures

28 29 30 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 1 - First study in Germany, focusing explicitly on person-centeredness in healthcare and social support services for women with unintended pregnancy
- 2 - Combination of quantitative and qualitative methods to ensure a comprehensive understanding of the women's perspectives
- 3 - Public involvement throughout all study phases, including an advisory board of women affected of an unintended pregnancy and an ethical advisory board
- 4 - Assessment will be limited by the lack of validated German measures for PC in this population

INTRODUCTION

The care situation of women with an unintended pregnancy is recently an important topic within political healthcare discussions in Germany [1,2]. The high relevance is reflected by several cases of lawsuits against the current legal regulations on abortion rights [2–6] as well as a reduction of the number of medical institutions performing abortions of almost 50% from 2021 to 2003 in Germany [7]. The federal statistical office counted 100.000 abortions per year for the past ten years [8]. Germany has around 780.000 livebirths per year [9], but there is no data on how many of these were livebirths of women who carried an unintended pregnancy to full term.

Currently, abortion is illegal under the German Criminal Code (§218 StGB [10]), but there are exemptions from punishment if one of the following conditions applies: 1) the pregnant individual obtained a mandatory “pregnancy-conflict counseling” and received a certificate of the counseling at least three days prior to the abortion procedure, and not more than 12 weeks have elapsed since conception; 2) there is a need to avert grave impairment to the physical or mental health of the pregnant individual; and 3) the pregnancy resulted from sexual assault or rape (§218 StGB [11]). The vast majority of abortions (95.8%) is conducted after the first condition [8].

Research, mainly conducted in the United States, shows that being unintendedly pregnant is associated with a number of social and health risks for the mother and the child as well as for the whole family [12–14]. These include increased risk behaviour during pregnancy, decreased mental health, increased family instability or domestic violence, and elevated preterm birth rates [12]. Compared to women who received an abortion, women who carry an unintended pregnancy to term because a wanted abortion was denied, more often live in economic hardship and with long-lasting insecurity [13].

1
2
3 1 In Germany, as well as in most developed western countries, patient-centeredness (PC), or
4
5 2 synonymously person-centeredness, has been defined as an important quality criterion in healthcare
6
7 3 and modern medicine [15]. PC includes different aspects of the healthcare context and defines a
8
9 4 relationship between healthcare professionals and individual that allows to put the preferences, needs
10
11 5 and values of the individual first [16]. In Germany, the Law on Patients' Rights mandates important
12
13 6 aspects of PC such as the right for comprehensible and comprehensive patient information [17].

14
15 7 Evidence-based recommendations for maternal and specifically abortion care for women with
16
17 8 unintended pregnancy highlight fundamental aspects of PC including informed decision-making,
18
19 9 confidentiality and privacy in healthcare, and access to legal and affordable care services [18,19].
20
21 10 However, this concept has not been found much practical relevance and appliance in healthcare for
22
23 11 women with an unintended pregnancy.

24
25 12 There are several studies focussing on general satisfaction in abortion care, but there is a lack of studies
26
27 13 on specific aspects of PC. A study from Tilles et al. [20,21] examined womens' overall satisfaction with
28
29 14 care during their first-trimester surgical abortion experience. Factors that increased womens' satisfaction
30
31 15 were a prompt appointment, courtesy of the staff, and provision of information. A study of McLemore et
32
33 16 al. [22] described ensured privacy to avoid shame or stigma, pain management, as well as the clinical
34
35 17 environment as influencing factors on satisfaction with abortion care.

36
37 18 The worldwide lack of PC in women's experiences of abortion care can be partly explained by restrictive
38
39 19 healthcare policies and social stigma associated with abortion [23]. In Germany, access to information
40
41 20 has been limited for almost 90 years by prohibiting healthcare providers to offer information on abortion
42
43 21 methods and conditions (§219a StGB). In June 2022, the German government has decided to delete
44
45 22 the respective paragraph and allow healthcare providers to offer information about abortion methods
46
47 23 and conditions for example on their websites. However, scientifically sound information on abortion
48
49 24 methods, conditions and addresses of adoption care providers is still rare in Germany and information
50
51 25 of anti-abortion initiatives is misleading.

52
53 26 Thus, to achieve high-quality PC care for women with unintended pregnancy in Germany, it is important
54
55 27 to assess the women's perspective on their experiences beyond satisfaction of care [18]. Currently, no
56
57 28 study on experiences of women with unintended pregnancy in healthcare and social support services in
58
59 29 Germany exists and also international research is limited. In 2019, the Federal German Health Ministry
60
30 has launched a funding priority on the "psychosocial situation and support needs of women with

1
2
3 1 unwanted pregnancy” and provided a funding volume of five million Euros, which was allocated to three
4
5 2 research projects, including CarePreg study at hand.

6 7 3 **Objectives**

8
9 4 The objectives of this mixed-methods study are 1) to identify the most relevant dimensions of PC in
10
11 5 healthcare and social support services for women with unintended pregnancy, 2) to evaluate PC within
12
13 6 the context of healthcare and social support services from the perspective of women with unintended
14
15 7 pregnancy, and 3) to develop recommendations for further actions in healthcare and social support
16
17 8 services for women with unintended pregnancy in Germany.

18
19 9

20 10 **METHODS AND ANALYSIS**

21 22 11 **Study design**

23
24 12 As a theoretical basis, this study will use the integrative model of patient-centeredness, encompassing
25
26 13 16 dimensions of PC [16,24,25]. It was originally developed by Scholl et al. based on a systematic review
27
28 14 on definitions of PC [16]. The model was validated by assessing the relevance of its dimensions in a
29
30 15 Delphi study with n=71 international experts [25] as well as a second Delphi study with n=214 patients
31
32 16 [24].

33
34 17 This three-year mixed methods CarePreg study uses a sequential exploratory design [26]. Thereby,
35
36 18 qualitative data and analysis inform the assessment of quantitative data and analysis. Final
37
38 19 interpretation was based on qualitative and quantitative results. The respective study design comprises
39
40 20 three phases. Each phase examines one of the objectives described above. An ethical advisory board
41
42 21 and an advisory board of women experienced an unintended pregnancy will be consulted by the
43
44 22 research team throughout all phases. Figure 1 gives an overview of the study phases. Details on each
45
46 23 phase will be described in the following paragraphs.

47
48 24

49 25 [PLEASE INSERT: Figure 1. Study design.]

50
51 26

52 53 27 **Study population**

54
55 28 This study will focus on individuals affected by an 'unintended' pregnancy. This umbrella term comprises
56
57 29 'unwanted' (e.g. individual do not want to have a child/be a parent), 'unplanned' (e.g. by accident or
58
59 30 mistake) and 'mistimed' (e.g. not the right time to become pregnant) pregnancies [27,28]. We

1
2
3 1 furthermore base our understanding of an unintended pregnancy on the definition of the authors of the
4
5 2 London Measure of Unplanned Pregnancy (LMUP): They rather defined unintended pregnancy on a
6
7 3 continuum between strictly planned and strictly unplanned pregnancies [28–30].

8
9 4 In the following, this manuscript uses the term “women” to describe the study population. Nevertheless,
10
11 5 non-binary individuals and trans men affected by an unintended pregnancy will be included as well. A
12
13 6 gender-neutral noun describing the pregnant individual (German: “Schwangere”) will be used in study
14
15 7 materials such as study information or questionnaires. Therefore, all individuals who sought or seek an
16
17 8 abortion and who carry or have carried a pregnancy to term will be included. Inclusion or exclusion
18
19 9 criteria differ slightly for the different phases and will be described below.

20
21 10 Prior to this study, we obtained collaboration agreements with several regional care facilities offering
22
23 11 psychosocial counseling or abortion services. These healthcare professionals will support the study by
24
25 12 recruiting participants, participate in expert workshops and adopt advisory functions.

26 13 27 28 14 **Phase 1: Identification of most relevant dimensions of PC**

29
30 15 Phase 1 aims to identify relevance and current implementation of the dimensions of the integrative PC
31
32 16 model for women with an unintended pregnancy. Thereby, qualitative expert workshops with healthcare
33
34 17 professionals and interviews with women who experienced an unintended pregnancy will be conducted.
35
36 18 Those methods are suitable to gain first insights in a research field by assessing personal experiences
37
38 19 and opinions [31,32]. Additionally, PC dimensions will be ranked according to their relevance and
39
40 20 implementation by healthcare professionals in an online survey.

41 21 ***Methodological approaches, participants, and measures***

42
43 22 Two online expert workshops will be conducted. We will include healthcare professionals for women
44
45 23 with an unintended pregnancy of different professions (e.g. social workers, counselors, or
46
47 24 gynaecologists). The workshops will be semi-structured based on the integrative model of PC [16]. The
48
49 25 16 dimensions of PC will be explained to the experts and they will be asked to elaborate on the
50
51 26 dimensions' relevance and actual implementation. Additionally, in a short online survey, experts were
52
53 27 asked to rank the 16 dimensions on a scale from 1 to 10 regarding relevance and current state of
54
55 28 implementation in Germany. The online survey will furthermore assess sociodemographic data of
56
57 29 experts (e.g. age, profession, work experience).

1
2
3 1 To evaluate the perspective of affected women, telephone interviews will be conducted. We will include
4
5 2 women who are at least 18 years old and who experienced an unintended pregnancy within the past
6
7 3 five years (ended in abortion or carried to term). A semi-structured interview guide will be developed.
8
9 4 The interview guide included questions on the women's experiences in healthcare and social support
10
11 5 services (e.g. "What were the most positive/negative experiences you have had with healthcare
12
13 6 professionals during the time of your unintended pregnancy?") as well as questions on needs and
14
15 7 wishes for optimal care (e.g. "What would you see in optimal care for individuals with an unintended
16
17 8 pregnancy?"). Additionally, sociodemographic data will be assessed (e.g. age group, education,
18
19 9 gestation age when pregnancy was discovered/aborted).

10 **Sample sizes and participant acquisition**

11 We aim to include 10 to 15 experts in online workshops. Experts will be invited via collaborating
12
13 12 institutions (e.g., social support services), personal contacts, and institutions or practices providing
14
15 13 healthcare for women with an unintended pregnancy, whose contact details are openly accessible on the
16
17 14 internet.

18 We aim to interview 15 to 20 women with a personal experience of unintended pregnancy. They will be
19
20 15 invited by collaborating institutions, through women health networks, personal contacts, and social
21
22 16 media posts on Twitter, Facebook, and Instagram.

18 **Data analysis**

19 The workshops and interviews will be audio-recorded, transcribed, and analyzed with qualitative content
20
21 20 analysis according to Mayring [32,33]. Thereby, the 16 dimensions of the integrative model of PC will
22
23 21 be defined as deductive categories [16,24]. One member of the research team (coder 1) will initially
24
25 22 code the first half of the data of the workshops and interviews separately. A second member of the
26
27 23 research team (coder 2) will code the second half of the data. Afterwards, coder 1 will review codings of
28
29 24 coder 2 and vice versa for quality control. Comparability of the coding schemes will be ensured by
30
31 25 regular meetings of the two coders throughout the whole coding process. Both will discuss codings and
32
33 26 coding scheme until consensus will be found.

28 **Phase 2: Evaluation of PC within medical care and social support services**

29 To assess PC within medical care and social support services from the perspective of women with an
30
31 30 unintended pregnancy, a mixed-methods approach using a quantitative longitudinal online survey and
32
33 60

1 qualitative semi-structured interviews with women with an unintended pregnancy will be applied. This
2 combination of methods allows an comprehensive understanding of factors that influenced quantitative
3 findings [34]. Results of phase 1 will inform the quantitative assessment in phase 2.

4 ***Methodological approaches, participants, and measures***

5 Phase 2 will include women who meet the following inclusion criteria: a) at least 18 years old, b) within
6 the first 24 weeks of an unintended pregnancy or sought abortion in accordance to §218 of the German
7 Criminal Code within the past eight weeks, and c) received counseling regarding their pregnancy (either
8 mandatory pregnancy conflict counseling or other psychosocial counseling).

9 Participants were asked to fill out the online survey at three measurement points: t0 (baseline), t1 (two
10 months after t0), t2 (12 months after t0).

11 The primary outcome of this study will be the *Experienced Patient-Centeredness Questionnaire (EPAT)*
12 [35]. This is a patient-reported experience measure developed on basis of the integrative model of PC
13 [16,25,36]. This measure will be applied at t0 and t1 and adapted to the context of healthcare for women
14 with an unintended pregnancy. For t0, the EPAT will be adapted to evaluate person-centeredness of
15 counseling in social support services. For t1, the EPAT will be adapted to evaluate person-centeredness
16 of medical care (in the context of abortion or pregnancy care).

17 Additionally, following measures will be applied:

18 Measures applied at t0 will focus on PC in counseling. Following measures will be applied additionally
19 to the adapted EPAT [35]: 1) the patient satisfaction questionnaire *ZUF-8* [37] to assess satisfaction
20 with counseling, 2) the translated and adapted *London Measure of Unplanned Pregnancy (LMUP)* [38]
21 to assess pregnancy intention/planning, 3) the adapted *NCCN distress thermometer* [39] to assess
22 emotional distress in the context of pregnancy determination, 4) self-developed questions on pregnancy
23 or abortion state (e.g. gestation age, weeks since abortion), and 5) demographic questions (e.g. age,
24 gestation age, weeks since abortion, relationship status, education, and financial income).

25 Measures applied at t1 will focus on PC in medical care. Following measures will be applied additionally
26 to the adapted EPAT [35]: 1) the *ZUF-8* [37] and 2) the *NCCN distress thermometer* [39], adapted to the
27 context of abortion and antenatal healthcare, and 3) self-developed questions on pregnancy or abortion
28 state (e.g. gestation age, weeks since abortion).

29 Measures applied at t2 will focus on a long-term evaluation of satisfaction with the decision, perceived
30 stigma and utilization of health care services. Following measures will be applied: 1) the German Version

1
2
3 1 of the *Decision Regret Scale (DRS)* [40] to evaluate satisfaction with the decision regarding the
4 pregnancy (abortion or carrying pregnancy to term), 2) the adapted *NCCN distress thermometer* [39],
5 2 pregnancy (abortion or carrying pregnancy to term), 2) the adapted *NCCN distress thermometer* [39],
6 3) the German version of the *Individual Level Abortion Stigma Scale* [41], 4) self-developed questions
7 3 3) the German version of the *Individual Level Abortion Stigma Scale* [41], 4) self-developed questions
8 4 on pregnancy or abortion state (e.g. gestation age, weeks since abortion), and 5) self-developed
9 4 on pregnancy or abortion state (e.g. gestation age, weeks since abortion), and 5) self-developed
10 5 questions on utilization of medical care and social services.
11 5 questions on utilization of medical care and social services.

12 6 Additional items might be developed depending on the results of phase 1.

13 7 To deepen results of the online survey, telephone-based interviews will be conducted with a subgroup
14 7 To deepen results of the online survey, telephone-based interviews will be conducted with a subgroup
15 8 of women who participated in the online survey. Women from both groups (carried pregnancy to term/
16 8 of women who participated in the online survey. Women from both groups (carried pregnancy to term/
17 9 aborted) will be included.
18 9 aborted) will be included.

19 10 **Sample sizes and participant acquisition**

20 11 Over a period of six months, cooperation partners (e.g. social support services, abortion providers) of
21 11 Over a period of six months, cooperation partners (e.g. social support services, abortion providers) of
22 12 this study will invite women to take part in the online survey. Our cooperation partners are primary
23 12 this study will invite women to take part in the online survey. Our cooperation partners are primary
24 13 located in Northern Germany. We will instruct them to invite all women, who met the inclusion criteria.
25 13 located in Northern Germany. We will instruct them to invite all women, who met the inclusion criteria.
26 14 There are only a few studies in Germany, which can be used as reference to estimate the response rate
27 14 There are only a few studies in Germany, which can be used as reference to estimate the response rate
28 15 of women with unintended pregnancy in Germany [42]. A study of Schmidt et al. including pregnant
29 15 of women with unintended pregnancy in Germany [42]. A study of Schmidt et al. including pregnant
30 16 women under the age of 18 could reach a response rate of 79% [42]. Thus, we aim to include a minimum
31 16 women under the age of 18 could reach a response rate of 79% [42]. Thus, we aim to include a minimum
32 17 of 600 participants at t0.
33 17 of 600 participants at t0.

34 18 For telephone-based interviews, we aim to include 15 to 20 women, who also participated in the online
35 18 For telephone-based interviews, we aim to include 15 to 20 women, who also participated in the online
36 19 survey.
37 19 survey.

38 20 **Data analysis**

39 21 Quantitative data of the online survey will be analyzed using descriptive statistics. If sample sizes allow,
40 21 Quantitative data of the online survey will be analyzed using descriptive statistics. If sample sizes allow,
41 22 differences between women who had an abortion and women who carried the pregnancy to term will be
42 22 differences between women who had an abortion and women who carried the pregnancy to term will be
43 23 analyzed with e.g. t-tests or Welch-tests. Qualitative interview data will be analyzed with qualitative
44 23 analyzed with e.g. t-tests or Welch-tests. Qualitative interview data will be analyzed with qualitative
45 24 content analysis by Mayring [33]. Data analyses will be conducted according to the procedure described
46 24 content analysis by Mayring [33]. Data analyses will be conducted according to the procedure described
47 25 for analysis of expert workshops in phase 1.
48 25 for analysis of expert workshops in phase 1.
49 26
50 26

51 26

52 27 **Phase 3: Identification of development needs in PC**

53 28 In phase 3, results of phase 1 and 2 will be integrated by the study team to identify healthcare needs.

54 29 In an expert workshop, recommendations for healthcare policy makers and healthcare professionals to
55 29 In an expert workshop, recommendations for healthcare policy makers and healthcare professionals to
56 30 improve PC in medical care and social support services for women with unintended pregnancy will be
57 30 improve PC in medical care and social support services for women with unintended pregnancy will be
58
59
60

1
2
3 1 derived. Additionally, recommendations will be rated in an online survey. This approach will allow to
4
5 2 develop evidence-based recommendations for practice and safeguard the relevance of the research
6
7 3 finding for relevant stakeholder.

4 ***Methodological approaches, participants, and measures***

5 Experts working with women with an unintended pregnancy (e.g., social workers, counselors of social
6 support services, gynaecologists) will be invited to take part in an online expert workshops. In the
7 workshop, the results of phase 1 and 2 will be presented by the study team. During the following semi-
8 structured discussion, we aim to develop a list of recommendations for actions to improve PC in medical
9 care and social support services for women with unintended pregnancy in Germany. These
10 recommendations will then be presented to a larger audience of experts in an online survey. Participants
11 of the survey will be asked to rate the list of recommendations regarding their relevance and feasibility.
12 In addition, demographic data of participants (e.g. age, profession, work experience) will be collected.

13 ***Sample sizes and participant acquisition***

14 We expect 10 to 15 experts to participate in the online workshop. They will be contacted by cooperation
15 partners, through personal contacts of the research team, and institutions or practices providing
16 healthcare for women with unintended pregnancy. Additionally, experts who participated in the expert
17 workshops of phase 1 will be asked to participate again.

18 For the online survey, we aim to include 100 – 150 experts from different institutions and regions in
19 Germany. Experts for the survey will be invited using the same strategies as for the online workshops.

20 ***Data analysis***

21 The online workshop will be audio-recorded and transcribed verbatim. For qualitative data analysis, a
22 pragmatic analysis approach will be adopted by using inductive thematic analysis [43,44]. One
23 researcher will identify recommendations in the transcripts and extract, cumulate and summarize them
24 into a document. Afterwards, relevance and wording of all recommendations will be discussed in the
25 research team until consensus is found. Quantitative data of the online survey will be analyzed using
26 descriptive statistics.

28 ***Software***

29 Online workshops will be facilitated via the meeting platform WebEx (Cisco Systems, Inc.). Audio
30 recordings of workshops and interviews will be transcribed using the software F4 transcript (dr. dressing

1
2
3 1 & pehl GmbH, Marburg). Qualitative data analysis will be supported by the software MAXQDA (VERBI
4
5 2 GmbH, Berlin). For quantitative data analyses, we will use the software IBM SPSS Statistics (IBM Corp.,
6
7 3 Armonk, NY).
8
9 4

10 5 **Patient and public involvement**

11
12 6 An advisory board including five to six women, who had experienced an unintended pregnancy within
13
14 7 in the past five years, will be involved during all phases of the study. The advisory board will include
15
16 8 women who decided to carry the pregnancy to term or to abort. Participation in the advisory board will
17
18 9 be voluntary and can be ended by the participants at any time. Following suggestions by Greenhalgh et
19
20 10 al. [45] for lay person and patient involvement, we aim to involve the advisory board in 1) project
21
22 11 management tasks such as recruitment of participants, design of study materials (e.g. study information,
23
24 12 questionnaires), and participation at ethical advisory meetings; 2) interpretation of results; and 3)
25
26 13 dissemination tasks such as producing summaries of findings for lay persons and advising dissemination
27
28 14 to lay people. Advisory board meeting will be held three to four times a year and will be evaluated using
29
30 15 mixed methods including the Public and Patient Engagement Evaluation Tool [46].
31
32 16

33 17 **ETHICS AND DISSEMINATION**

34 18 **Ethical and safety considerations**

35
36 19 The study will be carried out according to the latest version of the Helsinki Declaration of the World
37
38 20 Medical Association. Principles of good scientific practice will be respected. The study was approved by
39
40 21 Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical
41
42 22 Center Hamburg-Eppendorf, Germany (LPEK-0260). Standards of research ethics will be met. This
43
44 23 includes that study participation is voluntary and no foreseeable risks for participants result from the
45
46 24 participation. Participants will be fully informed about the aims of the study, data collection, and the use
47
48 25 of collected data. Written informed consent will be sought prior to participation. Preserving principles of
49
50 26 data sensitivity, data protection, and confidentiality requirements will be met.

51
52
53 27 In addition, a clinical ethics advisory board will advise the study team throughout the study regarding
54
55 28 questions of clinical ethics. The clinical ethical advisory board will comprise two to three experts from
56
57 29 the field (e.g., counselors, gynecologists), two experts for clinical ethics, and two women who
58
59 30 experienced an unintended pregnancy.
60

1 **Dissemination plan**

2 Every interested individual including all study participants will have the possibility to read and
3 download regular project updates and study results on the project website (www.uke.de/carepreg). In
4 addition, the results of the study will be published in international peer-reviewed scientific journals and
5 will be presented at national and international scientific conferences. Because of the relevance of the
6 topic for German healthcare professionals and counselors, the results will also be disseminated in
7 national journals. Those may include scientific, patient, policy, or public media outlets. If feasible, open
8 access publishing will be sought. Finally, the results will be reported back to the funder, the German
9 Federal Ministry of Health.

10 **Current state of the study**

11 The study started on November 1st, 2020. Phase 1 of the study has been completed. Quantitative
12 assessment of phase 2 is currently being prepared. Recruitment of participants for phase 2 has not yet
13 started. End of the study is April 30th 2024, according to current status.

15 **AUTHORS CONTRIBUTIONS**

16 JZ is the responsible primary investigator of the project and contributed to the specification of the
17 study design. JZ, PH, IS and MH conceptualized and designed the study. JZ wrote the grant proposal
18 and obtained funding. The first draft of this manuscript was written by JZ, PH, AL and LR. All authors
19 critically revised the manuscript for important intellectual content, gave final approval of the version to
20 be published and agree to be accountable for the work.

22 **COMPETING INTERESTS**

23 JZ, AL, LR, MH, IS and PH have no further competing interests.

25 **FUNDING STATEMENT**

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27 BMG) with the grant number 2520FSB113.

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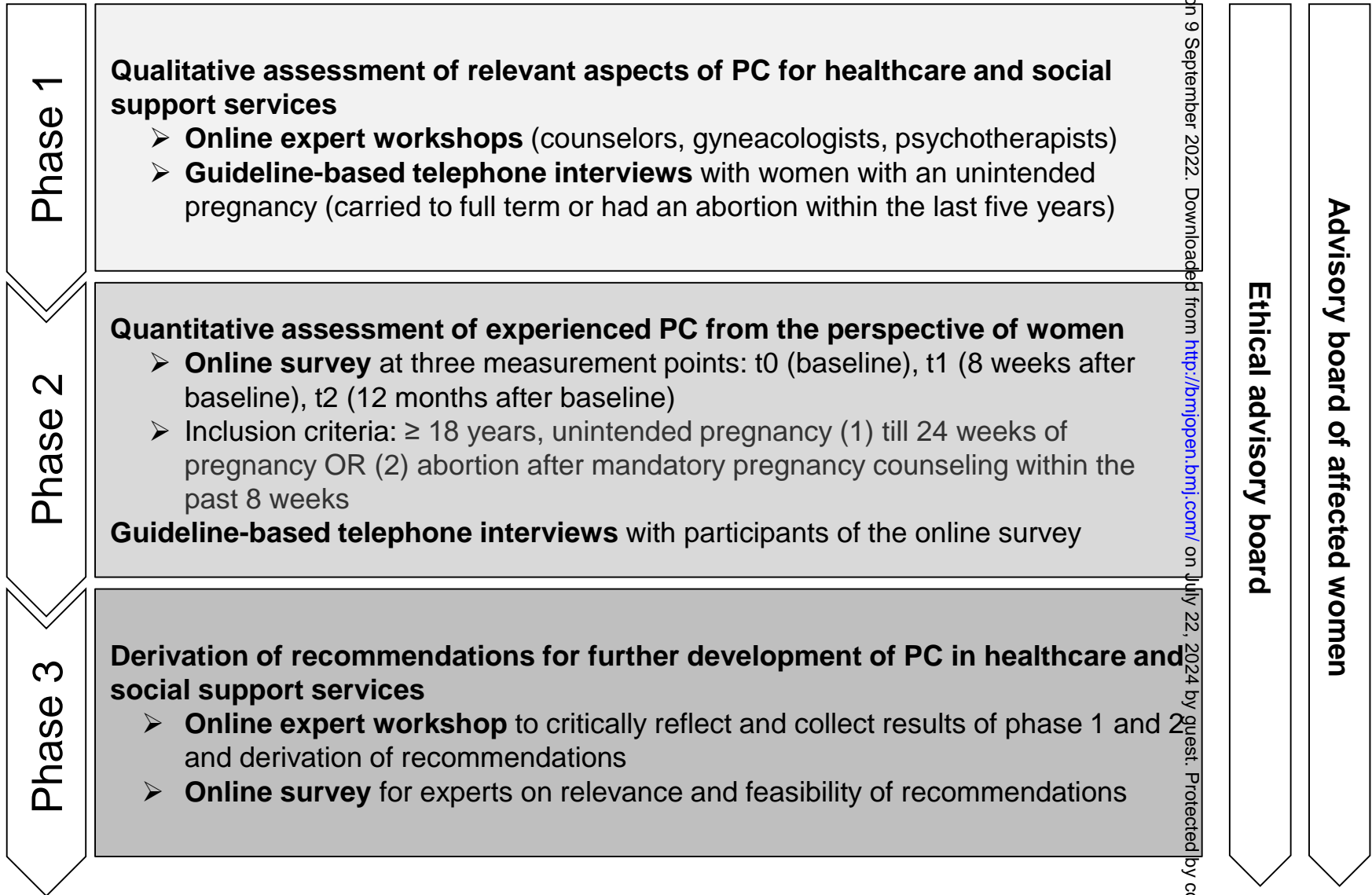
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Assessment of person-centeredness in healthcare and social support services for women with unintended pregnancy (CarePreg): protocol for a mixed-methods study

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3 1 **Assessment of person-centeredness in healthcare and social support services for women with**
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5 2 **unintended pregnancy (CarePreg): protocol for a mixed-methods study**
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1 **ABSTRACT**

2 **Introduction**

3 For women with unintended pregnancy, access to high-quality care has been found limited due to social
4 stigma and legal restrictions, especially when seeking abortion. To foster person-centeredness (PC),
5 recognizing the experiences and needs of women is the first premise. This study aims to 1) identify
6 relevant dimensions of PC 2) evaluate PC in healthcare and social support services, 3) develop
7 recommendations for further actions in healthcare and social support services – for women with
8 unintended pregnancy.

9 **Methods and analysis**

10 We will use a mixed-methods approach. Phase 1: expert workshops with 10 to 15 healthcare
11 professionals and counselors and semi-structured interviews with 15 to 20 women with unintended
12 pregnancy will be conducted to assess the relevance of PC dimensions. Phase 2: quantitative
13 assessment of PC dimensions within healthcare and support services will be conducted. We aim to
14 include 600 women with an unintended pregnancy a) until 24 weeks of pregnancy or b) who sought
15 abortion within the past eight weeks, over three measurement points within twelve months. To deepen
16 the results, semi-structured interviews will be conducted. Phase 3, a workshop with 10 to 15 experts
17 and an online survey with 100 to 150 experts will be used to indicate recommendations. Participants will
18 be gained through relevant care facilities. An ethical advisory board and an advisory board of affected
19 women will be involved throughout the study.

20 **Ethics and dissemination**

21 The study will be carried out in accordance to the latest version of the Helsinki Declaration of the World
22 Medical Association and principles of good scientific practice. The study was approved by the Local
23 Psychological Ethics Committee of the University Medical Center Hamburg-Eppendorf, Germany
24 (LPEK-0260). Written informed consent will be sought prior to study participation. The study results will
25 be disseminated in scientific journals, through collaboration partners and plain language press releases.

26

27 **Keywords:** person-centeredness; patients' experiences, unintended pregnancy; abortion care;
28 pregnancy care; mixed-methods; patient-reported experience measures

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3 1 In Germany, as well as in most developed western countries, patient-centeredness (PC), or
4
5 2 synonymously person-centeredness, has been defined as an important quality criterion in healthcare
6
7 3 and modern medicine [15]. PC includes different aspects of the healthcare context and defines a
8
9 4 relationship between healthcare professionals and individual that allows to put the preferences, needs
10
11 5 and values of the individual first [16]. In Germany, the Law on Patients' Rights mandates important
12
13 6 aspects of PC such as the right for comprehensible and comprehensive patient information [17].

14
15 7 Evidence-based recommendations for maternal and specifically abortion care for women with
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17 8 unintended pregnancy highlight fundamental aspects of PC including informed decision-making,
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19 9 confidentiality and privacy in healthcare, and access to legal and affordable care services [18,19].
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21 10 However, this concept has not been found much practical relevance and appliance in healthcare for
22
23 11 women with an unintended pregnancy.

24
25 12 There are several studies focussing on general satisfaction in abortion care, but there is a lack of studies
26
27 13 on specific aspects of PC. A study from Tilles et al. [20,21] examined women's overall satisfaction with
28
29 14 care during their first-trimester surgical abortion experience. Factors that increased women's satisfaction
30
31 15 were a prompt appointment, courtesy of the staff, and provision of information. A study of McLemore et
32
33 16 al. [22] described ensured privacy to avoid shame or stigma, pain management, as well as the clinical
34
35 17 environment as influencing factors on satisfaction with abortion care.

36
37 18 The worldwide lack of PC in women's experiences of abortion care can be partly explained by restrictive
38
39 19 healthcare policies and social stigma associated with abortion [23]. In Germany, access to information
40
41 20 has been limited for almost 90 years by prohibiting healthcare providers to offer information on abortion
42
43 21 methods and conditions (§219a StGB). In June 2022, the German government has decided to delete
44
45 22 the respective paragraph and allow healthcare providers to offer information about abortion methods
46
47 23 and conditions for example on their websites. However, scientifically sound information on abortion
48
49 24 methods, conditions and addresses of adoption care providers is still rare in Germany and information
50
51 25 of anti-abortion initiatives is misleading.

52
53 26 Thus, to achieve high-quality PC care for women with unintended pregnancy in Germany, it is important
54
55 27 to assess the women's perspective on their experiences beyond satisfaction of care [18]. Currently, no
56
57 28 study on experiences of women with unintended pregnancy in healthcare and social support services in
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59 29 Germany exists and also international research is limited. In 2019, the Federal German Health Ministry
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30 has launched a funding priority on the "psychosocial situation and support needs of women with

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3 1 unwanted pregnancy” and provided a funding volume of five million Euros, which was allocated to three
4
5 2 research projects, including CarePreg study at hand.

6 7 3 **Objectives**

8
9 4 The objectives of this mixed-methods study are 1) to identify the most relevant dimensions of PC in
10
11 5 healthcare and social support services for women with unintended pregnancy, 2) to evaluate PC within
12
13 6 the context of healthcare and social support services from the perspective of women with unintended
14
15 7 pregnancy, and 3) to develop recommendations for further actions in healthcare and social support
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17 8 services for women with unintended pregnancy in Germany.

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20 10 **METHODS AND ANALYSIS**

21 22 11 **Study design**

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24 12 As a theoretical basis, this study will use the integrative model of patient-centeredness, encompassing
25
26 13 16 dimensions of PC [16,24,25]. It was originally developed by Scholl et al. based on a systematic review
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28 14 on definitions of PC [16]. The model was validated by assessing the relevance of its dimensions in a
29
30 15 Delphi study with n=71 international experts [25] as well as a second Delphi study with n=214 patients
31
32 16 [24].

33
34 17 This three-year mixed-methods CarePreg study uses a sequential exploratory design [26]. Thereby,
35
36 18 qualitative data and analysis inform the assessment of quantitative data and analysis. Final
37
38 19 interpretation was based on qualitative and quantitative results. The respective study design comprises
39
40 20 three phases. Each phase examines one of the objectives described above. An ethical advisory board
41
42 21 and an advisory board of women experienced an unintended pregnancy will be consulted by the
43
44 22 research team throughout all phases. Figure 1 gives an overview of the study phases. Details on each
45
46 23 phase will be described in the following paragraphs.

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49 25 **Study population**

50
51 26 This study will focus on individuals affected by an 'unintended' pregnancy. This umbrella term comprises
52
53 27 'unwanted' (e.g. individual do not want to have a child/be a parent), 'unplanned' (e.g. by accident or
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55 28 mistake) and 'mistimed' (e.g. not the right time to become pregnant) pregnancies [27,28]. We
56
57 29 furthermore base our understanding of an unintended pregnancy on the definition of the authors of the

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3 1 London Measure of Unplanned Pregnancy (LMUP): They rather defined unintended pregnancy on a
4
5 2 continuum between strictly planned and strictly unplanned pregnancies [28–30].
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7 3 In the following, this manuscript uses the term “women” to describe the study population. Nevertheless,
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9 4 non-binary individuals and trans men affected by an unintended pregnancy will be included as well. A
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11 5 gender-neutral noun describing the pregnant individual (German: “Schwangere”) will be used in study
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13 6 materials such as study information or questionnaires. Therefore, all individuals who sought or seek an
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15 7 abortion and who carry or have carried a pregnancy to term will be included. Inclusion or exclusion
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17 8 criteria differ slightly for the different phases and will be described below.

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19 9 Prior to this study, we obtained collaboration agreements with several regional care facilities offering
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21 10 psychosocial counseling or abortion services. These healthcare professionals will support the study by
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23 11 recruiting participants, participate in expert workshops and adopt advisory functions.
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26 13 **Phase 1: Identification of most relevant dimensions of PC**

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28 14 Phase 1 aims to identify relevance and current implementation of the dimensions of the integrative PC
29
30 15 model for women with an unintended pregnancy. Thereby, qualitative expert workshops with healthcare
31
32 16 professionals and interviews with women who experienced an unintended pregnancy will be conducted.
33
34 17 Those methods are suitable to gain first insights in a research field by assessing personal experiences
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36 18 and opinions [31,32]. Additionally, PC dimensions will be ranked according to their relevance and
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38 19 implementation by healthcare professionals in an online survey.

39 20 ***Methodological approaches, participants, and measures***

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41 21 Two online expert workshops will be conducted. We will include healthcare professionals for women
42
43 22 with an unintended pregnancy of different professions (e.g. social workers, counsellors, or
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45 23 gynaecologists). The workshops will be semi-structured based on the integrative model of PC [16]. The
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47 24 16 dimensions of PC will be explained to the experts and they will be asked to elaborate on the
48
49 25 dimensions’ relevance and actual implementation. Additionally, in a short online survey, experts were
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51 26 asked to rank the 16 dimensions on a scale from 1 to 10 regarding relevance and current state of
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53 27 implementation in Germany. The online survey will furthermore assess sociodemographic data of
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55 28 experts (e.g. age, profession, work experience).

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57 29 To evaluate the perspective of affected women, telephone interviews will be conducted. We will include
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59 30 women who are at least 18 years old and who experienced an unintended pregnancy within the past
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3 1 five years (ended in abortion or carried to term). A semi-structured interview guide will be developed.
4
5 2 The interview guide included questions on the women's experiences in healthcare and social support
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7 3 services (e.g. "*What were the most positive/negative experiences you have had with healthcare*
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9 4 *professionals during the time of your unintended pregnancy?*") as well as questions on needs and
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11 5 wishes for optimal care (e.g. "*What would you see in optimal care for individuals with an unintended*
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13 6 *pregnancy?*"). Additionally, sociodemographic data will be assessed (e.g. age group, education,
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15 7 gestation age when pregnancy was discovered/aborted).

8 **Sample sizes and participant acquisition**

9 We aim to include 10 to 15 experts in online workshops. Experts will be invited via collaborating
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11 10 institutions (e.g., social support services), personal contacts, and institutions or practices providing
12
13 11 healthcare for women with an unintended pregnancy, whose contact details are openly accessible on the
14
15 12 internet.

16
17 13 We aim to interview 15 to 20 women with a personal experience of unintended pregnancy. They will be
18
19 14 invited by collaborating institutions, through women health networks, personal contacts, and social
20
21 15 media posts on Twitter, Facebook, and Instagram.

16 **Data analysis**

17 The workshops and interviews will be audio-recorded, transcribed, and analyzed with qualitative content
18
19 18 analysis according to Mayring [32,33]. Thereby, the 16 dimensions of the integrative model of PC will
20
21 19 be defined as deductive categories [16,24]. One member of the research team (coder 1) will initially
22
23 20 code the first half of the data of the workshops and interviews separately. A second member of the
24
25 21 research team (coder 2) will code the second half of the data. Afterwards, coder 1 will review codings of
26
27 22 coder 2 and vice versa for quality control. Comparability of the coding schemes will be ensured by
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29 23 regular meetings of the two coders throughout the whole coding process. Both will discuss codings and
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31 24 coding scheme until consensus will be found.

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52 **Phase 2: Evaluation of PC within medical care and social support services**

53 To assess PC within medical care and social support services from the perspective of women with an
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55 28 unintended pregnancy, a mixed-methods approach using a quantitative longitudinal online survey and
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57 29 qualitative semi-structured interviews with women with an unintended pregnancy will be applied. This
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3 1 combination of methods allows an comprehensive understanding of factors that influenced quantitative
4
5 2 findings [34]. Results of phase 1 will inform the quantitative assessment in phase 2.

6 7 3 ***Methodological approaches, participants, and measures***

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9 4 Phase 2 will include women who meet the following inclusion criteria: a) at least 18 years old, b) within
10
11 5 the first 24 weeks of an unintended pregnancy or sought abortion in accordance to §218 of the German
12
13 6 Criminal Code within the past eight weeks, and c) received counseling regarding their pregnancy (either
14
15 7 mandatory pregnancy conflict counseling or other psychosocial counseling).

16
17 8 Participants were asked to fill out the online survey at three measurement points: t0 (baseline), t1 (two
18
19 9 months after t0), t2 (12 months after t0).

20
21 10 The primary outcome of this study will be the *Experienced Patient-Centeredness Questionnaire (EPAT)*
22
23 11 [35]. This is a patient-reported experience measure developed on basis of the integrative model of PC
24
25 12 [16,25,36]. This measure will be applied at t0 and t1 and adapted to the context of healthcare for women
26
27 13 with an unintended pregnancy. For t0, the EPAT will be adapted to evaluate person-centeredness of
28
29 14 counseling in social support services. For t1, the EPAT will be adapted to evaluate person-centeredness
30
31 15 of medical care (in the context of abortion or pregnancy care).

32
33 16 Additionally, following measures will be applied:

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35 17 Measures applied at t0 will focus on PC in counseling. Following measures will be applied additionally
36
37 18 to the adapted EPAT [35]: 1) the patient satisfaction questionnaire *ZUF-8* [37] to assess satisfaction
38
39 19 with counseling, 2) the translated and adapted *London Measure of Unplanned Pregnancy (LMUP)* [38]
40
41 20 to assess pregnancy intention/planning, 3) the adapted *NCCN distress thermometer* [39] to assess
42
43 21 emotional distress in the context of pregnancy determination, 4) self-developed questions on pregnancy
44
45 22 or abortion state (e.g. gestation age, weeks since abortion), and 5) demographic questions (e.g. age,
46
47 23 gestation age, weeks since abortion, relationship status, education, and financial income).

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49 24 Measures applied at t1 will focus on PC in medical care. Following measures will be applied additionally
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51 25 to the adapted EPAT [35]: 1) the *ZUF-8* [37] and 2) the *NCCN distress thermometer* [39], adapted to the
52
53 26 context of abortion and antenatal healthcare, and 3) self-developed questions on pregnancy or abortion
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55 27 state (e.g. gestation age, weeks since abortion).

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57 28 Measures applied at t2 will focus on a long-term evaluation of satisfaction with the decision, perceived
58
59 29 stigma and utilization of health care services. Following measures will be applied: 1) the German Version
60
30 of the *Decision Regret Scale (DRS)* [40] to evaluate satisfaction with the decision regarding the

1 pregnancy (abortion or carrying pregnancy to term), 2) the adapted *NCCN distress thermometer* [39],
2 3) the German version of the *Individual Level Abortion Stigma Scale* [41], 4) self-developed questions
3 on pregnancy or abortion state (e.g. gestation age, weeks since abortion), and 5) self-developed
4 questions on utilization of medical care and social services.

5 Additional items might be developed depending on the results of phase 1.

6 To deepen results of the online survey, telephone-based interviews will be conducted with a subgroup
7 of women who participated in the online survey. Women from both groups (carried pregnancy to term/
8 aborted) will be included.

9 **Sample sizes and participant acquisition**

10 Over a period of six months, cooperation partners (e.g. social support services, abortion providers) of
11 this study will invite women to take part in the online survey. Our cooperation partners are primary
12 located in Northern Germany. We will instruct them to invite all women, who met the inclusion criteria.
13 There are only a few studies in Germany, which can be used as reference to estimate the response rate
14 of women with unintended pregnancy in Germany [42]. A study of Schmidt et al. including pregnant
15 women under the age of 18 could reach a response rate of 79% [42]. Thus, we aim to include a minimum
16 of 600 participants at t0.

17 For telephone-based interviews, we aim to include 15 to 20 women, who also participated in the online
18 survey.

19 **Data analysis**

20 Quantitative data of the online survey will be analyzed using descriptive statistics. If sample sizes allow,
21 differences between women who had an abortion and women who carried the pregnancy to term will be
22 analyzed with e.g. t-tests or Welch-tests. Qualitative interview data will be analyzed with qualitative
23 content analysis by Mayring [33]. Data analyses will be conducted according to the procedure described
24 for analysis of expert workshops in phase 1.

26 **Phase 3: Identification of development needs in PC**

27 In phase 3, results of phase 1 and 2 will be integrated by the study team to identify healthcare needs.
28 In an expert workshop, recommendations for healthcare policy makers and healthcare professionals to
29 improve PC in medical care and social support services for women with unintended pregnancy will be
30 derived. Additionally, recommendations will be rated in an online survey. This approach will allow to

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3 1 develop evidence-based recommendations for practice and safeguard the relevance of the research
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5 2 finding for relevant stakeholder.

6 7 3 ***Methodological approaches, participants, and measures***

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9 4 Experts working with women with an unintended pregnancy (e.g., social workers, counsellors of social
10
11 5 support services, gynaecologists) will be invited to take part in an online expert workshops. In the
12
13 6 workshop, the results of phase 1 and 2 will be presented by the study team. During the following semi-
14
15 7 structured discussion, we aim to develop a list of recommendations for actions to improve PC in medical
16
17 8 care and social support services for women with unintended pregnancy in Germany. These
18
19 9 recommendations will then be presented to a larger audience of experts in an online survey. Participants
20
21 10 of the survey will be asked to rate the list of recommendations regarding their relevance and feasibility.
22
23 11 In addition, demographic data of participants (e.g. age, profession, work experience) will be collected.

24 25 12 ***Sample sizes and participant acquisition***

26
27 13 We expect 10 to 15 experts to participate in the online workshop. They will be contacted by cooperation
28
29 14 partners, through personal contacts of the research team, and institutions or practices providing
30
31 15 healthcare for women with unintended pregnancy. Additionally, experts who participated in the expert
32
33 16 workshops of phase 1 will be asked to participate again.

34
35 17 For the online survey, we aim to include 100 – 150 experts from different institutions and regions in
36
37 18 Germany. Experts for the survey will be invited using the same strategies as for the online workshops.

38 39 19 ***Data analysis***

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41 20 The online workshop will be audio-recorded and transcribed verbatim. For qualitative data analysis, a
42
43 21 pragmatic analysis approach will be adopted by using inductive thematic analysis [43,44]. One
44
45 22 researcher will identify recommendations in the transcripts and extract, cumulate and summarize them
46
47 23 into a document. Afterwards, relevance and wording of all recommendations will be discussed in the
48
49 24 research team until consensus is found. Quantitative data of the online survey will be analyzed using
50
51 25 descriptive statistics.

52 53 27 ***Software***

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55 28 Online workshops will be facilitated via the meeting platform WebEx (Cisco Systems, Inc.). Audio
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57 29 recordings of workshops and interviews will be transcribed using the software F4 transcript (dr. dresing
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59 30 & pehl GmbH, Marburg). Qualitative data analysis will be supported by the software MAXQDA (VERBI

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3 1 GmbH, Berlin). For quantitative data analyses, we will use the software IBM SPSS Statistics (IBM Corp.,
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5 2 Armonk, NY).
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9 4 **Patient and public involvement**

10 5 An advisory board including five to six women, who had experienced an unintended pregnancy within
11 6 in the past five years, will be involved during all phases of the study. The advisory board will include
12 7 women who decided to carry the pregnancy to term or to abort. Participation in the advisory board will
13 8 be voluntary and can be ended by the participants at any time. Following suggestions by Greenhalgh et
14 9 al. [45] for lay person and patient involvement, we aim to involve the advisory board in 1) project
15 10 management tasks such as recruitment of participants, design of study materials (e.g. study information,
16 11 questionnaires), and participation at ethical advisory meetings; 2) interpretation of results; and 3)
17 12 dissemination tasks such as producing summaries of findings for lay persons and advising dissemination
18 13 to lay people. Advisory board meeting will be held three to four times a year and will be evaluated using
19 14 mixed-methods including the Public and Patient Engagement Evaluation Tool [46].
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32 16 **ETHICS AND DISSEMINATION**

33 17 **Ethical and safety considerations**

34 18 The study will be carried out according to the latest version of the Helsinki Declaration of the World
35 19 Medical Association. Principles of good scientific practice will be respected. The study was approved by
36 20 Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical
37 21 Center Hamburg-Eppendorf, Germany (LPEK-0260). Standards of research ethics will be met. This
38 22 includes that study participation is voluntary and no foreseeable risks for participants result from the
39 23 participation. Participants will be fully informed about the aims of the study, data collection, and the use
40 24 of collected data. Written informed consent will be sought prior to participation. Preserving principles of
41 25 data sensitivity, data protection, and confidentiality requirements will be met.
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51 26 In addition, a clinical ethics advisory board will advise the study team throughout the study regarding
52 27 questions of clinical ethics. The clinical ethical advisory board will comprise two to three experts from
53 28 the field (e.g., counselors, gynecologists), two experts for clinical ethics, and two women who
54 29 experienced an unintended pregnancy.
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1 **Dissemination plan**

2 Every interested individual including all study participants will have the possibility to read and
3 download regular project updates and study results on the project website (www.uke.de/carepreg). In
4 addition, the results of the study will be published in international peer-reviewed scientific journals and
5 will be presented at national and international scientific conferences. Because of the relevance of the
6 topic for German healthcare professionals and counselors, the results will also be disseminated in
7 national journals. Those may include scientific, patient, policy, or public media outlets. If feasible, open
8 access publishing will be sought. Finally, the results will be reported back to the funder, the German
9 Federal Ministry of Health.

10 **Status of the study**

11 The study started on November 1st, 2020. Phase 1 of the study has been completed. Quantitative
12 assessment of phase 2 is currently being prepared. Recruitment of participants for phase 2 has not yet
13 started. End of the study is April 30th 2024, based on the current status.

15 **CONTRIBUTORS**

16 JZ is the responsible primary investigator of the project and contributed to the specification of the
17 study design. JZ, PH, IS and MH conceptualized and designed the study. JZ wrote the grant proposal
18 and obtained funding. The first draft of this manuscript was written by JZ, PH, AL and LR. All authors
19 critically revised the manuscript for important intellectual content, gave final approval of the version to
20 be published and agree to be accountable for the work.

21 **COMPETING INTERESTS**

22 JZ, AL, LR, MH, IS and PH have no further competing interests.

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4 experienced an unintended pregnancy and to the members of our clinical ethics advisory board.

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1 **Figure title**

2 **Figure 1. Study design**

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Qualitative assessment of relevant aspects of PC for healthcare and social support services

- **Online expert workshops** (counselors, gynecologists, psychotherapists)
- **Guideline-based telephone interviews** with women with an unintended pregnancy (carried to full term or had an abortion within the last five years)

Quantitative assessment of experienced PC from the perspective of women

- **Online survey** at three measurement points: t0 (baseline), t1 (8 weeks after baseline), t2 (12 months after baseline)
- Inclusion criteria: ≥ 18 years, unintended pregnancy (1) till 24 weeks of pregnancy OR (2) abortion after mandatory pregnancy counseling within the past 8 weeks

Guideline-based telephone interviews with participants of the online survey

Derivation of recommendations for further development of PC in healthcare and social support services

- **Online expert workshop** to critically reflect and collect results of phase 1 and 2 and derivation of recommendations
- **Online survey** for experts on relevance and feasibility of recommendations

Ethical advisory board

Advisory board of affected women