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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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ABSTRACT

Introduction

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

Methods and analysis

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

Ethics and dissemination

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

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

STRENGTHS AND LIMITATIONS OF THIS STUDY

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- First study in Germany, focusing explicitly on person-centeredness in healthcare and social support services for women with unintended pregnancy
- Combination of quantitative and qualitative methods to ensure a comprehensive understanding of the women's perspectives
- Public involvement throughout all study phases, including an advisory board of women affected of an unintended pregnancy and an ethical advisory board
- 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].

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

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

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

The worldwide lack of PC in women's experiences of abortion care can be partly explained by restrictive healthcare policies and social stigma associated with abortion [23]. In Germany, access to information has been limited for almost 90 years by prohibiting healthcare providers to offer information on abortion methods and conditions (§219a StGB). In June 2022, the German government has decided to delete the respective paragraph and allow healthcare providers to offer information about abortion methods and conditions for example on their websites. However, scientifically sound information on abortion methods, conditions and addresses of adoption care providers is still rare in Germany and information of anti-abortion initiatives is misleading.

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

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unwanted pregnancy" and provided a funding volume of five million Euros, which was allocated to three research projects, including CarePreg study at hand.

Objectives

The objectives of this mixed-methods study are 1) to identify the most relevant dimensions of PC in healthcare and social support services for women with unintended pregnancy, 2) to evaluate PC within the context of healthcare and social support services from the perspective of women with unintended pregnancy, and 3) to develop recommendations for further actions in healthcare and social support services for women with unintended pregnancy in Germany.

METHODS AND ANALYSIS

Study design

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

This three-year mixed methods CarePreg study uses a sequential exploratory design [26]. Thereby, qualitative data and analysis inform the assessment of quantitative data and analysis. Final interpretation was based on qualitative and quantitative results. The respective study design comprises three phases. Each phase examines one of the objectives described above. An ethical advisory board and an advisory board of women experienced an unintended pregnancy will be consulted by the research team throughout all phases. Figure 1 gives an overview of the study phases. Details on each phase will be described in the following paragraphs.

[PLEASE INSERT: Figure 1. Study design.]

Study population

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

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

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

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

Phase 1: Identification of most relevant dimensions of PC

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

Methodological approaches, participants, and measures

Two online expert workshops will be conducted. We will include healthcare professionals for women with an unintended pregnancy of different professions (e.g. social workers, counselors, or gynaecologists). The workshops will be semi-structured based on the integrative model of PC [16]. The 16 dimensions of PC will be explained to the experts and they will be asked to elaborate on the dimensions’ relevance and actual implementation. Additionally, in a short online survey, experts were asked to rank the 16 dimensions on a scale from 1 to 10 regarding relevance and current state of implementation in Germany. The online survey will furthermore assess sociodemographic data of experts (e.g. age, profession, work experience).

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

Sample sizes and participant acquisition

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

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

Data analysis

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

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

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

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

Methodological approaches, participants, and measures

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

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

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

Additionally, following measures will be applied:

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

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

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

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

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

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

Sample sizes and participant acquisition

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

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

Data analysis

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

Phase 3: Identification of development needs in PC

In phase 3, results of phase 1 and 2 will be integrated by the study team to identify healthcare needs. In an expert workshop, recommendations for healthcare policy makers and healthcare professionals to improve PC in medical care and social support services for women with unintended pregnancy will be

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

Methodological approaches, participants, and measures

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

Sample sizes and participant acquisition

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

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

Data analysis

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

Software

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

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& pehl GmbH, Marburg). Qualitative data analysis will be supported by the software MAXQDA (VERBI GmbH, Berlin). For quantitative data analyses, we will use the software IBM SPSS Statistics (IBM Corp., Armonk, NY).

Patient and public involvement

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

ETHICS AND DISSEMINATION

Ethical and safety considerations

The study will be carried out according to the latest version of the Helsinki Declaration of the World Medical Association. Principles of good scientific practice will be respected. The study was approved by Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf, Germany (LPEK-0260). Standards of research ethics will be met. This includes that study participation is voluntary and no foreseeable risks for participants result from the participation. Participants will be fully informed about the aims of the study, data collection, and the use of collected data. Written informed consent will be sought prior to participation. Preserving principles of data sensitivity, data protection, and confidentiality requirements will be met.

In addition, a clinical ethics advisory board will advise the study team throughout the study regarding questions of clinical ethics. The clinical ethical advisory board will comprise two to three experts from the field (e.g., counselors, gynecologists), two experts for clinical ethics, and two women who experienced an unintended pregnancy.

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Dissemination plan

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

Current state of the study

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

AUTHORS CONTRIBUTIONS

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

COMPETING INTERESTS

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

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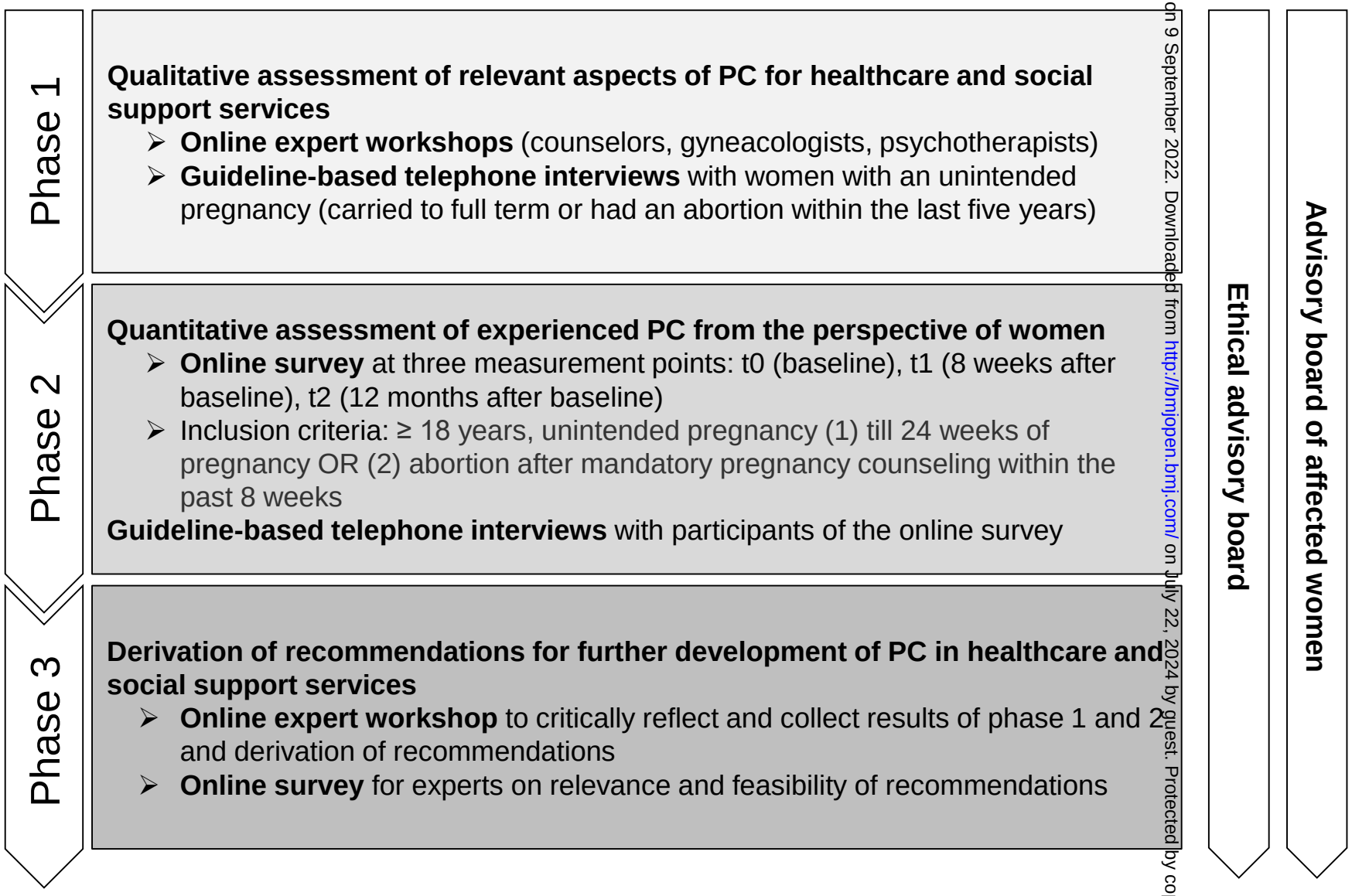

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Assessment of person-centeredness in healthcare and social support services for women with unintended pregnancy (CarePreg): protocol for a mixed-methods study

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ABSTRACT

Introduction

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

Methods and analysis

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

Ethics and dissemination

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

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

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STRENGTHS AND LIMITATIONS OF THIS STUDY

- Combination of quantitative and qualitative methods to ensure a comprehensive understanding of the women's perspectives.
- Public involvement throughout all study phases, including an advisory board of women affected of an unintended pregnancy and an ethical advisory board.
- Assessment will be limited by the lack of validated German measures for person-centeredness 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 with 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].

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

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

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

The worldwide lack of PC in women's experiences of abortion care can be partly explained by restrictive healthcare policies and social stigma associated with abortion [23]. In Germany, access to information has been limited for almost 90 years by prohibiting healthcare providers to offer information on abortion methods and conditions (§219a StGB). In June 2022, the German government has decided to delete the respective paragraph and allow healthcare providers to offer information about abortion methods and conditions for example on their websites. However, scientifically sound information on abortion methods, conditions and addresses of adoption care providers is still rare in Germany and information of anti-abortion initiatives is misleading.

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

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unwanted pregnancy" and provided a funding volume of five million Euros, which was allocated to three research projects, including CarePreg study at hand.

Objectives

The objectives of this mixed-methods study are 1) to identify the most relevant dimensions of PC in healthcare and social support services for women with unintended pregnancy, 2) to evaluate PC within the context of healthcare and social support services from the perspective of women with unintended pregnancy, and 3) to develop recommendations for further actions in healthcare and social support services for women with unintended pregnancy in Germany.

METHODS AND ANALYSIS

Study design

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

This three-year mixed-methods CarePreg study uses a sequential exploratory design [26]. Thereby, qualitative data and analysis inform the assessment of quantitative data and analysis. Final interpretation was based on qualitative and quantitative results. The respective study design comprises three phases. Each phase examines one of the objectives described above. An ethical advisory board and an advisory board of women experienced an unintended pregnancy will be consulted by the research team throughout all phases. Figure 1 gives an overview of the study phases. Details on each phase will be described in the following paragraphs.

Study population

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

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London Measure of Unplanned Pregnancy (LMUP): They rather defined unintended pregnancy on a continuum between strictly planned and strictly unplanned pregnancies [28–30].

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

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

Phase 1: Identification of most relevant dimensions of PC

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

Methodological approaches, participants, and measures

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

To evaluate the perspective of affected women, telephone interviews will be conducted. We will include women who are at least 18 years old and who experienced an unintended pregnancy within the past

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five years (ended in abortion or carried to term). A semi-structured interview guide will be developed. The interview guide included questions on the women's experiences in healthcare and social support services (e.g. "*What were the most positive/negative experiences you have had with healthcare professionals during the time of your unintended pregnancy?"*) as well as questions on needs and wishes for optimal care (e.g. *"What would you see in optimal care for individuals with an unintended pregnancy?*"). Additionally, sociodemographic data will be assessed (e.g. age group, education, gestation age when pregnancy was discovered/aborted).

Sample sizes and participant acquisition

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

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

Data analysis

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

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

To assess PC within medical care and social support services from the perspective of women with an unintended pregnancy, a mixed-methods approach using a quantitative longitudinal online survey and qualitative semi-structured interviews with women with an unintended pregnancy will be applied. This

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combination of methods allows an comprehensive understanding of factors that influenced quantitative findings [34]. Results of phase 1 will inform the quantitative assessment in phase 2.

Methodological approaches, participants, and measures

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

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

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

Additionally, following measures will be applied:

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

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

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

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

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

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

Sample sizes and participant acquisition

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

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

Data analysis

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

Phase 3: Identification of development needs in PC

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

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

Methodological approaches, participants, and measures

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

Sample sizes and participant acquisition

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

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

Data analysis

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

Software

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

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GmbH, Berlin). For quantitative data analyses, we will use the software IBM SPSS Statistics (IBM Corp., Armonk, NY).

Patient and public involvement

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

ETHICS AND DISSEMINATION

Ethical and safety considerations

The study will be carried out according to the latest version of the Helsinki Declaration of the World Medical Association. Principles of good scientific practice will be respected. The study was approved by Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf, Germany (LPEK-0260). Standards of research ethics will be met. This includes that study participation is voluntary and no foreseeable risks for participants result from the participation. Participants will be fully informed about the aims of the study, data collection, and the use of collected data. Written informed consent will be sought prior to participation. Preserving principles of data sensitivity, data protection, and confidentiality requirements will be met.

In addition, a clinical ethics advisory board will advise the study team throughout the study regarding questions of clinical ethics. The clinical ethical advisory board will comprise two to three experts from the field (e.g., counselors, gynecologists), two experts for clinical ethics, and two women who experienced an unintended pregnancy.

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Dissemination plan

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

Status of the study

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

CONTRIBUTORS

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

COMPETING INTERESTS

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

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1 **Figure title**

2 **Figure 1. Study design**

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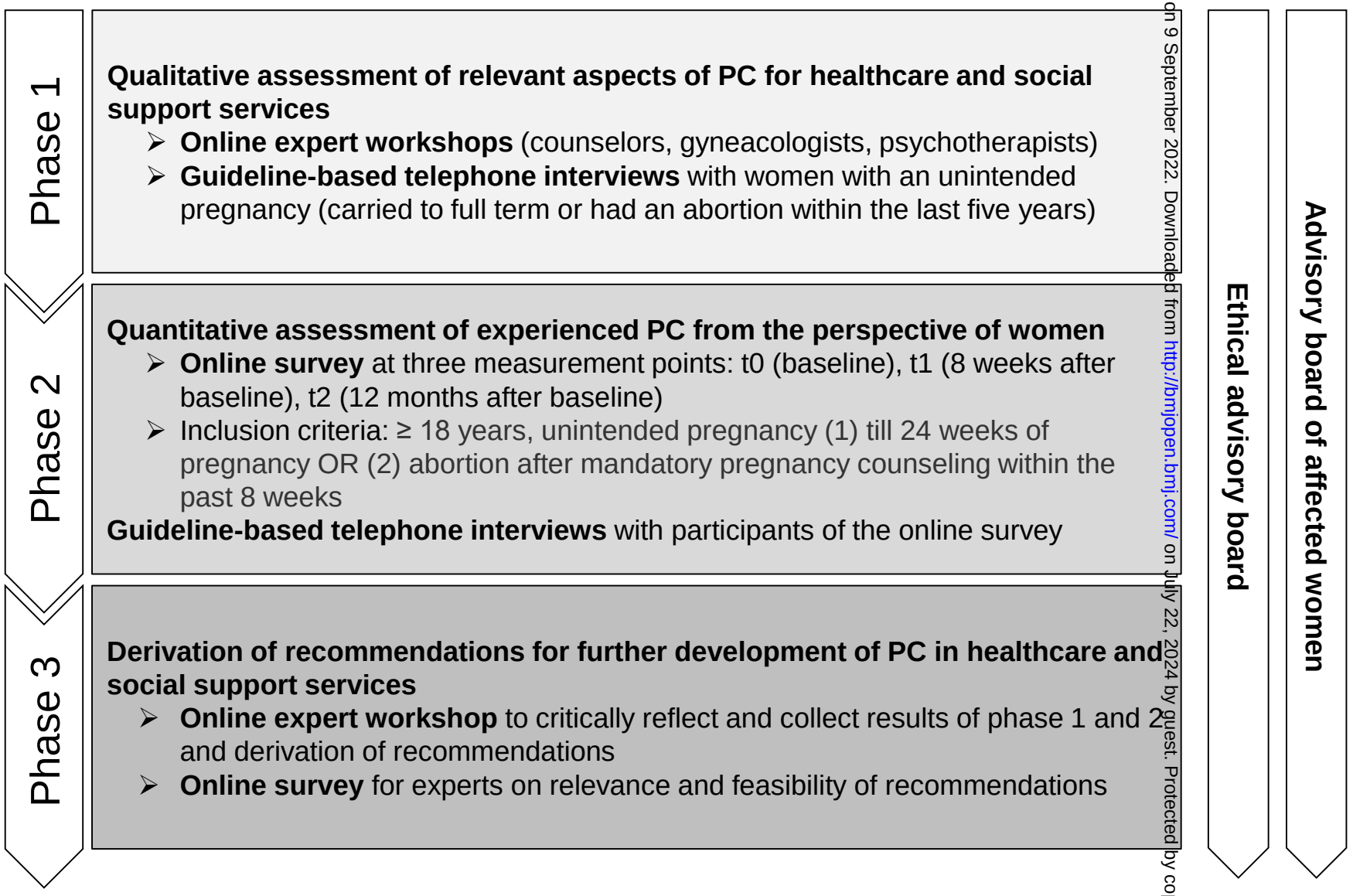

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