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The PinK Study – Methodology of the Baseline Survey of a Prospective Cohort Study of Couples undergoing Fertility Treatment

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The PinK Study – Methodology of the Baseline Survey of a Prospective Cohort Study of Couples undergoing Fertility Treatment

Abstract

This paper describes the realization of the baseline survey of the study 'PinK- Paare in Kinderwunschbehandlung' (couples undergoing fertility treatment). The study aims at a broader and better understanding of the situation of couples with an unfulfilled desire to have a child and of pathways leading couples to the fertility clinic. The approach of the study is interdisciplinary. It is designed as a prospective cohort study in a clinical setting. The study population consists of couples with an unfulfilled desire to have a child who presented themselves in a fertility clinic in the German state of Rhineland-Palatinate (RP) or in the capital city of the state of Hesse between July 2012 and May 2013. Self-administered questionnaires were used to gather information from patients at fertility clinics. These were handed out to the patients by the staff at the fertility clinics. Questionnaires returned by the end of July 2013 were included in the data set. The final sample consists of 323 female and 242 male respondents. In 234 couples, both partners participated. The overall response rate is 31%, with considerable variation across the clinics – reasons for and consequences of this are discussed. The final sample is described in terms of the distribution of core socio-demographic variables.

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1 Introduction

The goal of this paper is to document the study design and the data collection process for the baseline survey of the study 'PinK- Paare in Kinderwunschbehandlung' (couples undergoing fertility treatment). Additionally a description of the sample based on core socio-demographic variables is provided. The PinK Study is an ongoing prospective cohort study of couples with an unfulfilled desire to have a child, who consecutively presented themselves in a fertility clinic in the German state of Rhineland-Palatinate (RP) or in the capital city of the state of Hesse, Wiesbaden. Self-administered questionnaires were used to gather information from these patients in 2012/13.

The PinK Study aims to better understand the pathways leading to fertility treatment and the situation of couples with an unfulfilled desire to have a child. The design of the study and the research are guided by the following research questions:

- What are potential barriers to go to the fertility clinic and what factors facilitate access to the clinic from a patient perspective?
- What are the characteristics of individuals and couples consulting fertility clinics?
- What are the psychological and social consequences of the experience of infertility and fertility treatment for the individual and for the couple?

The approach of the study is interdisciplinary. Researchers from several disciplines such as medicine, public health, psychology, sociology and demography contribute to this study. The PinK research group consists of researchers from four institutions: Institute of Occupational, Social and Environmental Medicine at the University Medical Center of the Johannes Gutenberg University Mainz (ASU); Federal Institute for Population Research, Wiesbaden (BiB); Evangelische Hochschule Darmstadt - University of Applied Sciences (EHD) and Department of Obstetrics and Gynecology at the University Medical Center of the Johannes Gutenberg University Mainz. The study center was located at the ASU.

To our knowledge this is the first prospective cohort study on the situation of couples undergoing fertility treatment in Germany using an interdisciplinary approach, covering a broad range of research questions and including both partners. Documentation starts with a brief introduction into the topic of infertility and assisted reproductive technologies in Germany (Section 2), followed by a description of the design of the PinK Study (Section 3). Section 4 describes the pretest and its results. This is followed by an overview of the study materials handed out to the patients at the fertility clinics and of the content of the questionnaire (Section 5.1 and Section 5.2). In Section 6 response rates are presented and discussed. Section 7 gives an overview of the data handling, description of the sample and sensitivity analysis. The paper ends with a discussion (Section 8).

2 Background: Infertility and Assisted Reproductive Technology in Germany

Infertility, jointly defined by the World Health Organization (WHO) and the International Committee for Monitoring Assisted Reproductive Technologies (ICMART) as 'failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse' (Zegers-Hochschild et al. 2009: 1522) is often a devastating experience for couples with a desire for a child. Lifetime prevalence of infertility for women between 20 and 44 years of age who were 'ever at risk' of becoming pregnant is estimated at 21% in

Germany (Helfferich 2001: 305).[1] In other words, every fifth woman experiences a period of at least twelve months of infertility during her reproductive period. The risk of infertility increases with age and since women have delayed their first births to higher ages the incidence of age-related infertility in women has also increased in the past (ESHRE Capri Workshop Group 2005: 261). Women in Germany and in other European countries keep delaying first births (Bujard et al. 2012: 49), hence age-related infertility will most likely increase further as well as the demographic relevance of the issue.

Assisted reproductive technologies (ART) such as in vitro fertilization (IVF), intracytoplasmatic sperm injection (ICSI), cryo-transfer and insemination have increasingly become an important course of action for couples affected by infertility in Germany as in most other European countries (Ferraretti et al. 2013). This becomes evident when looking at the data provided by the German IVF Registry on a yearly basis (Bühler et al. 2012, Bühler et al. 2013). In the year 2011, 128 specialized fertility clinics provided their services to patients with fertility problems in Germany. The number of clinics has constantly been on the rise since 1996. For 2011 the IVF Registry documented 78,922 plausible-treatment cycles of IVF, ICSI, a combination of IVF and ICSI and cryo-transfer[2] among 49,696 women, resulting in 13,567 live births. These represent 2% of all births in Germany in 2011 (Statistisches Bundesamt 2014a, authors' calculation). For the year 2008 Ferraretti et al. (2013: 5) calculated the percentage of 'ART infants per national births' in 19 European countries generated from European registers by the European Society of Human Reproduction and Embryology (ESHRE). This provides a benchmark to compare with the situation in Germany: According to their data 1.5% of all children were born after ART in Germany, but there was considerable variation between European countries ranging from 0.6% ART infants per national births in Moldavia and 4.5% in Denmark and Slovenia.

National and regional regulation of general eligibility criteria and of reimbursement schemes for fertility treatment costs restrict access to fertility treatments in Germany. Thereby they pose crucial constraints for individuals and couples with fertility problems considering medical treatment for infertility and are briefly described below. General eligibility criteria are formulated in a guideline covering assisted reproduction by the German Medical Association (Bundesärztekammer), the central organization in the German medical self-administration system. According to this document, eligibility is generally restricted to married couples, but under certain conditions allowed for unmarried couples (Bundesärztekammer 2006). The guideline has been adopted by most of the 17 State Chambers of Physicians including Hesse and Rhineland Palatinate (RP), which makes it binding for doctors practicing reproductive medicine in these federal states. Thus, for our research it is important to look at married as well as unmarried couples. No differences in general eligibility criteria are to be expected for Hesse and RP.

Reimbursement schemes for fertility treatment vary between private and statutory health insurance in Germany. This is important since treatment costs are considerable and may therefore pose another constraint to treatment. Wischmann (2012: 77) roughly estimates the full cost for one IVF cycle between 2,000 and 4,000 € and for one ICSI cycle between 2,500 and 5,000 €. In 2012, statutory health insurance covered about 69.7 million people (Bundesministerium für Gesundheit 2012) of 80.4 million residents (Statistisches Bundesamt 2014b). Until December 2003, up to 4 treatment cycles were fully covered by statutory health insurance. Since January 2004 the law for the modernization of the statutory health insurance applies. Since then only 50% of the

[1] 'Ever at risk' is defined as having had unprotected sexual intercourse at least once (ibid: 305). This lifetime prevalence measure can only be considered an estimated value since the women asked were still in their reproductive period.

[2] Other less invasive treatment options such as intrauterine insemination (IUI), which are also typically offered in fertility clinics, are not covered in the IVF registry. We do not know of any sources that provide data on number of treatments for these treatment options. Generally one would expect higher percentage of births after ART if they were included.

treatment costs for a maximum of three treatment cycles are reimbursed. For couples to qualify for coverage they must be married; women must be between 25 and 40 years of age and men between 25 and 50 years of age. The data provided by the German IVF Registry show a major reduction in the number of fertility treatments performed in 2004 compared to the years 2002 and 2003. The number is recovering since, but has not yet reached the level of 2002 (Bühler et al. 2012). According to Dietrich and Wevers (2010) the extreme increase in co-payments is a major reason for the decline.

Since implementation of the GMG, some statutory health insurance providers have individually increased coverage of fertility treatments for their customers. In April 2012 the German Federal government started an initiative ('Bundesförderrichtlinie') to support fertility patients financially and thereby reduce patient co-payments from 50 to 25% (Bundesministerium für Familie, Senioren, Frauen und Jugend 2012). This is conditional on cooperation of the federal states, which have to share the costs equally with the Federal government. To date, five states have negotiated and signed a corresponding agreement with the Federal government. RP and Hesse did not participate in 2012/2013; hence co-payments remain at the 50% level. The situation for patients with private insurance is somewhat different. Private insurance providers mostly provide full coverage according to the cost-by-cause principle. Employees of the Federal Armed Forces are exempted from the general compulsory insurance scheme. According to General Administrative Regulation infertility treatment was not covered by military health care at the time of the Pink Study (VwV 869, Abs. 2 BBesG).

3 Study Design

This section provides a detailed description of the design of the PinK Study, a prospective cohort study using self-administered questionnaires as the mode of data collection. Self-administered questionnaires are especially useful for sensitive topics such as that of the PinK Study, because no interviewer is present and there is little time pressure (de Leeuw/Hox 2008: 244). The target population for the basline survey consists of heterosexual couples with fertility problems who are about to start fertility treatment in RP or Wiesbaden, as this constitutes the group for which this option is available in those federal states. This target group was chosen in order to gain insights into the situation of couples at the beginning of treatment. A postal follow-up survey was planned one year after each respondent's first participation starting in July 2013. It will allow us to investigate what happened since the couples started fertility treatment and to describe their current situation. By contrast to other studies, we are interested not only in the perspective of women, as is often the case when fertility is concerned, but to also gain insights into the perspective of men and thereby allow for comparisons of women and men and for analyses of differences and similarities in couples.

Standard representative and probability-based sampling techniques did not seem effective for approaching this very specific and small study population. Accordingly, we decided to conduct a prospective cohort study and recruit respondents directly from fertility clinics. Compared to alternative sampling strategies such as ads on thematically related websites inviting visitors of those sites to participate in an online survey, a well-designed study where respondents are recruited in fertility clinics offers more opportunities to control the recruiting process. It allows us to apply eligibility criteria to arrive at a clearly defined, homogenous and distinguishable cohort of couples beginning fertility treatment.

A set of three eligibility criteria was applied. This was communicated to the participating clinics along with the request to hand out study packages to all patients who matched

the criteria (for a description of the content of the study packages see Section 5.1). If all couples to which the eligibility criteria applied had been addressed and participated in the baseline survey of the PinK Study, the study population would have been identical with the target population of interest.

The eligibility criteria are the following:

1. At least one partner should have sufficient skills in German or Turkish.
   As questionnaires were provided in German and Turkish, at least one partner had to be able to read and understand either language.

2. At least one partner should have his/her primary residence in Germany.
   Couples were excluded if both partners did not reside in Germany. This restriction was necessary because patients at German fertility clinics do not have to be German residents. Non-residents are mostly 'reproductive tourists' and might include patients from a diverse set of neighbouring and non-neighbouring countries. Their cultural, legal and socio-economic backgrounds might differ extensively from that of couples living in Germany. Moreover their situation concerning financing fertility treatments might differ.

3. Timing: All patients who participated in the first patient briefing on treatment(s) planned (German: 'Aufklärungs-/Prozedere-Gespräch') at the respective clinic concerning their current unfulfilled desire to have a child.

   This point in time was chosen over the first appointment at the clinic in order to reduce patient burden at the first visit and not to interfere in the doctor-patient relationship at this early stage. In all cases the patient briefing should be about the first treatment in the respective clinic concerning the current desire to have a child. This implies that couples who had switched fertility clinics and individuals/couples who had fertility treatment before for an earlier desire to have child are included. Couples just starting another treatment (cycle) at the respective clinic are excluded. The term 'treatment' refers to all kinds of treatments offered at a fertility clinic (e.g. Intrauterine insemination, cycle monitoring, IVF) and is not restricted to the invasive treatments monitored by the German IVF Registry (cf. Section 2). The intention of this criterion is to fix the stage in the process fertility treatment when patients receive the questionnaires. We assume that answers to some questions would be sensitive to the stage, e.g. stress might be perceived differently at the beginning of treatment than after two unsuccessful IVF cycles. Handing out the study packages at the patient briefing was not conditional on both partners being present.

In order to hold state-level differences in legal regulation of general eligibility for treatment and in treatment coverage constant, recruitment of respondents was originally restricted regionally to the state of RP. All fertility clinics situated in RP (n=5) agreed to participate in the study: Universitäts-Kinderwunschzentrum Mainz, Kinderwunsch Zentrum Mainz, Kinderwunschzentrum Ludwigshafen, Kinderwunschzentrum Mittelrhein and Kinderwunsch Praxisklinik Trier.[3] We estimated it would take between 4-6 months to arrive at the target sample size of approximately 500 couples. This estimation was based on the approximate number of new patients per year in each participating clinic as reported by each clinic upon request and the response rates from the standard pretest (see Section 4). However, the response rate for the first four months was considerably lower than expected. The recruitment strategy was expanded to include the Kinderwunschzentrum Wiesbaden (Hesse). At that time there were no substantial differences in the regulation of general eligibility for treatment and in treatment coverage in RP and Hesse (cf. Section 2). Hesse and RP are neighboring federal states in southwest Germany. In 2012, 3.9 million people were living in RP compared to 6.0 million in Hesse

[3] The Kinderwunschzentrum Mittelrhein has one clinic in Neuwied and one in Koblenz. The Kinderwunsch Zentrum Mainz has one clinic in Mainz and one in Worms (all cities in RP). These are not treated as separate clinics here.

(Statistisches Bundesamt 2013a). The capital cities Wiesbaden (Hesse) and Mainz (RP) are geographically very close and situated in the Rhine-Main metropolitan region, whereas Ludwigshafen (RP) is located in the Rhine-Neckar metropolitan region. Both are populous and economically rather strong regions in Germany. Koblenz and Trier are situated in more rural areas with 107,954 and 106,284 inhabitants each (Statistisches Bundesamt 2013b).

Study packages were handed out to the patients by a doctor or other staff with regular patient contact from July 2012 until May 2013 in RP and in Wiesbaden (Hesse) from December 4, 2012 until May 2013. Patients were asked to complete the questionnaire alone and at home and to send it back to the study center in stamped, self-addressed envelopes. All clinics were provided with a stock of bilingual study packages in German and Turkish in order to include patients without sufficient skills in German in the study.[4] Bilingual study packages were supposed to be handed out to couples were the clinic staff suspected language difficulties.

Before the start of the baseline survey, training and information sessions were conducted at each participating clinic to which all staff was invited. Sessions were held by two members of the research group. Each session consisted of a short lecture and time for the staff to ask questions. Important topics in the information sessions were the goals of the PinK Study, eligibility criteria and how to handle the study packages of members of the target population who refused to participate in the study. As response rate calculations are based on the number of study packages handed out, each study package could be 'used' only once. Therefore the respective study packages of non-respondents had to be discarded and not returned to the pile for distribution. At the end of the sessions a contact person was nominated in each clinic as the person in charge of the PinK Study.

Study materials were given to the contact person by a member of the PinK research group before the start of the baseline survey. They were accompanied by several copies of an instruction sheet for the staff concerning the eligibility criteria, how to handle questionnaires of non-respondents, when to hand out the bilingual study packages and recommendations for what to say to the patients. It was important to motivate the patients to participate, while also informing patients that their participation was voluntary and that their anonymity would be assured at all times. The number of study packages distributed to the clinics was calculated separately for each clinic, based on the number of new patients per year. Therefore the number handed out to each clinic varied.[5] The first stock of study packages which was provided before the start of the study was calculated to last for approximately two months, but since opening the field coincided with school holidays in RP and Christmas break in Hesse, it was expected to last a bit longer than two months. A fax form was provided to order new study packages. Additionally, as the response rates were constantly monitored by the study center, this information could be used to assess the number of study packages left at the clinics. They were proactively contacted if the stock was running low. At the end of the distribution period leftovers were picked up from each clinic.

In order to promote the study at the clinics they were provided with flyers in German and Turkish and posters to lay or hang in the waiting rooms or elsewhere in the clinics. Both the flyer and poster compile some general information about the study and were also supposed to serve as a reminder to participate for patients who had received a study package during a previous visit to the clinic (see Appendix 10.1 for images).

[4] Turkish was the foreign language for which the fertility clinics reported the greatest need.
[5] Due to lack of space some clinics asked for a smaller quantity of study packages.

The study center tried to keep in close contact with the fertility clinics in order to monitor distribution of study packages, keep up motivation and to become aware of problems early. Two weeks after the start of the baseline survey all clinics were called to ask for the number of study packages already handed out and to check if the staff at the clinics had any questions. Further calls were made every few weeks throughout the whole distribution period. Still, oftentimes the contact person or other staff could not be reached. They were often occupied or not available for other reasons such as vacation or part-time work. After two months a motivation letter was sent to each clinic, which was addressed to the contact person and other staff involved in the distribution of the study packages at each clinic. It was used to thank the staff for their effort and to inform them about the total number of questionnaires already returned. The topic of patient motivation was addressed once again.

Due to the study design the research group had no access to individual patient data or contact information of those patients to which study packages were handed out at any time. It was not possible to re-contact patients and send a reminder, a measure that is commonly recommended to increase response rates in postal surveys. This also means that it was not possible to directly investigate patterns of non-response.

As a postal follow-up survey was planned all respondents were asked for their willingness to participate in a follow-up survey and if this was the case, to provide their contact information on a contact form provided in the study packages. Two separate stamped envelopes were provided to the respondents to return the questionnaire and the contact form separately. Since the contact form contained full names and addresses of the respondents, this measure served to secure their anonymity as the two documents could not be linked. To underline this, both envelopes were addressed to different destinations. Whereas the envelope for the questionnaire was addressed to the study center, the envelope for the contact form was addressed to the BiB.

Additonally, measures had to be taken to be able to match respondents' questionnaires from the baseline and follow-up survey. Personal codes generated by the respondents were used. They are recommended in settings where sensitivity to issues of anonymity and data protection is high (Schnell et al. 2006: 129). Personal codes normally have a length of six to ten characters and consist of parts of time-constant characteristics of respondents such as their birth date or place of birth (ibid: 129). Study design and materials for the main study were approved by the data protection commissioners and the ethical commitee of the State Boards of Physicians of Rhineland Palatinate and Hesse.

4 Pretest

A pretest was performed before the start of the baseline survey. Qualitative and quantitative pretesting was combined based on the strategy of multi-method pretesting as proposed by Prüfer and Rexroth (2000).

The pretest mainly served the following objectives:

1. to test central concepts and specifically developed questions of the questionnaire
2. to get an impression of the willingness and motivation of potential respondents to participate in a study covering sensitive issues
3. to test the coordination between study center and fertility clinics and the processes within the fertility clinics

The qualitative pretest mainly served the first objective, while the quantitative pretest focused on the other two objectives. Due to time restrictions, both parts of the pretest were implemented simultaneously and not sequentially as originally proposed by Prüfer and Rexroth. All pretests were designed and organized by the research group. [The pretests were approved by the data protection commissioner and the ethical commitee of the State Board of Physicians of Rhineland Palatinate].

For the qualitative pretest, the technique of cognitive interviewing was applied to probe the comprehension of specific questions, central terms and concepts that reappeared throughout the questionnaire. A guideline was used for all semi-structured cognitive interviews. Several cognitive techniques were employed throughout the interview: comprehension probing, information retrieval probing, category selection probing, general probing and paraphrasing (cf. e.g. Prüfer/Rexroth 2005). At the end of each interview the participants were asked to rate three pictures that had been considered for use on the cover page of the questionnaire.

It was important that the interviews be completed with members of the target population of the PinK Study. Participants were recruited in collaboration with the Universitäts-Kinderwunschzentrum Mainz between December 2011 and March 2012. The head of the fertility clinic invited patients to participate in a qualitative interview. He briefly informed the patients about the purpose of the study and what would be asked of them. They received a letter containing detailed information about the goals of the study and the procedure of the pretest. Anonymity was assured and they were informed that they would be remunerated for their efforts with 30 € per person. If they were willing to participate they were asked to sign a declaration of consent and allow interviewers to contact them to arrange a personal interview. Questionnaires were handed out to them, which were supposed to be completed and brought to the interview. Overall six couples participated in the qualitative pretest. They were invited to the study center. Both partners were interviewed separately by one of three interviewers. The interviews of approximately 1-hour duration were audiotaped if approved by the respondent. This allowed interviewers to fully concentrate on talking to the participants. Interviews were not transcribed, but served to aid recall for the interviewers who prepared a protocol of each interview.

Simultaneously, a standard pretest was performed in four fertility clinics with members of the target population. All clinics in RP with the exception of the Universitäts-Kinderwunschzentrum Mainz participated in the standard pretest. Each of the four clinics was provided with instructions and ten study packages in a large envelope. Study packages for the pretest contained study materials for both partners, which were separately packed in two smaller envelopes. The study materials for each partner included an information letter, a questionnaire, an evaluation sheet and a self-addressed and stamped return envelope. The letter informed the respondents about the goals of the study and the pretest. The issues of anonymity and data privacy protection were raised and measures taken to ensure it were described. In order to participate in the pretest, respondents were asked to complete the questionnaire and the evaluation sheet and send both back to the study center. The purpose of the evaluation sheet was to provide concise feedback about the study. It consisted of eleven questions: six questions about the questionnaire itself, two questions about the overall willingness of the respondents to participate in a prospective study, one question where respondents were asked to generate a personal code and one where they were asked if this was difficult for them and finally one open question for general remarks.

45 of 80 persons participated in the quantitative pretest, which results in an overall individual level response rate of 56%.[6] There were no major differences between men

[6] Calculation is based on the assumption that all questionnaires were handed out to patients and that questionnaires of couples who had refused to participate were not returned to the pile of study packages and used again.

and women: 24 women and 21 men sent back questionnaires. There was considerable variation in the response rates among the fertility clinics (range: 20-95%). To some extent the dissimilarities were expected to result from the composition of the residential population in different parts of the state and hence from the patients in the fertility clinics. Fertility clinics are situated in urban as well as more rural settings. It was perceived that the topic of privacy is much more prevalent in rural than in urban regions. Additionally, efforts taken by the staff of the clinics to motivate potential respondents might have differed. Another plausible explanation is that patients were selected not only based on eligibility criteria but also on their motivation or their level of education. As selection based on attributes other than the eligibility criteria was potentially a severe source of selectivity, the issue had to be tackled in the main study. Therefore, as already described in chapter 3, training and information sessions were conducted at each clinic, information materials were provided to the staff at the clinics and it was tried to keep close contact to the staff at the clinics.

Overall the response rates of the standard pretest were motivating. Some clinics achieved very good response rates, suggesting that there was considerable interest in the topic of the study among patients. On the evaluation sheet 34 of 45 respondents rated the topic of the study '(very) interesting' (cf. Appendix 10.2 for exact wording and answer categories of the questions analyzed here). 19 of 45 respondents rated the questionnaire as 'a bit/much too long.' Generally the respondents had few problems generating a personal code: only 2 respondents reported 'minor difficulties.' The extensive pretesting resulted in several changes to the questionnaire, mostly changes in question wording but also in the order of questions. Although most respondents did not find the questionnaire too long, it was shortened to reduce the burden on the respondents. The picture that was rated best in the qualitative pretest was used on the cover page of the questionnaires and on study materials such as flyers and posters.

5 Study Materials

In order to increase response rates when self-administered questionnaires are used, special attention needs to be paid to the 'visual presentation' of the study materials (de Leeuw/Hox 2008: 240). This was especially important as it was not possible to send advance letters and a reminder. Section 5.1 provides an overview of the content of the study packages that were handed out to patients at the fertility clinics. This is followed by a description of the design and content of the final questionnaire of the baseline survey in Section 5.2.

5.1 Study Packages

Study packages for the main study were handed out to patients in the participating fertility clinics in a large envelope containing all materials for both partners, separately packed in transparent pockets. Table 1 shows an overview of the materials, which were packed in the described order. The Turkish study packages, however, contained materials in Turkish as well as in German, leaving it up to the patients which language they preferred.

Table 1: Content of study packages for the baseline survey of the PinK Study

No.	Women	Men
1	Cover sheet women	Cover sheet men
2	Information letter women	Information letter men
3	Questionnaire women	Questionnaire men
4	Stamped return envelope (ASU) for questionnaire (A4 format)	Stamped return envelope (ASU) for questionnaire (A4 format)
5	Contact form (follow-up survey)	Contact form (follow-up survey)
6	Stamped return envelope (BiB) for contact form (long format)	Stamped return envelope (BiB) for contact form (long format)

Cover sheets were gender specific for clarity's sake. The picture rated best in the pretest was printed on the cover sheet for both sexes. Respondents are asked to complete the questionnaire alone, without interruption and without help from others and to send it back to the study center in the enclosed envelope.

The letter informed patients about the goals of the PinK Study, the research institutions involved and the importance of the patient's participation. As in the pretest the issues of anonymity and data privacy protection were raised and measures taken to ensure it were described. The letter also informed patients about the purpose of the ID printed on each page of the questionnaire and that it could not be used to identify them. Information letters were signed by the coordinator of the baseline survey and the director of the BiB. A short guide to filling in the questionnaire was printed on the rear of the information letter.

A logo for the PinK Study was designed and used on all study materials to increase recognition value of the materials. The PinK logo was accompanied by the logos of the major researchers of the baseline survey, the ASU and the BiB. The logos were intended to indicate that it was a scientific and not a commercial study. The same design elements were used on all study materials (see Appendix 10.1 for examples). The information letter, the cover sheet of the questionnaire, flyers and posters contain contact information for respondents who have any questions about the study. Contact was possible either by e-mail or telephone.

5.2 Questionnaire

The questionnaire of the PinK Study covers a broad range of topics. It is divided into 10 major sections. It starts with a retrospective account of the pathways leading couples to their first visit in a fertility clinic with specific emphasis on potential external and internal barriers from the patient's perspective (module 1-2). It continues with questions about the upcoming fertility treatment (e.g. treatments proposed by doctor; module 3) and financing of treatments (module 4). The following section focuses on the reproductive biography of the respondents as well as their current unfulfilled desire to have a child and how it affects the spousal relationship and other areas of life (module 5). Modules 6 and 7 cover attitudes and relationship biography. This is followed by a module covering health issues (module 8); while the purpose of the two subsequent sections is to gather socio-demographic data (module 9-10). The final section informs respondents about the planned follow-up study, asks if respondents are interested in participating and, if this is the case, they are asked to generate a personal code that would be used to match respondents' questionnaires from the main and follow-up study (module 11). The questionnaire consists of 84 questions, mostly closed-ended questions and few open-

ended questions. Filters were used only rarely, as this is oftentimes a source of error in self-administered questionnaires. The time needed to complete the questionnaire was expected to be 30 to 40 minutes.

An important aspect in designing the questionnaire was to allow comparisons between the PinK study population and the German general population. Therefore, the PinK questionnaire used questions from other population surveys such as the German Health Update (GEDA; Robert Koch-Institut 2012a), the German Generations and Gender Survey (GGS; Ruckdeschel et al. 2009), the German Family Panel 'pairfam' (Huinink et al. 2011) and the German Microcensus (Statistisches Bundesamt/GESIS 2014), if feasible. In some cases minor adaptations were carried out because of a different survey mode in the original survey. Additionally, several scales from the Danish Multi-centre Psychosocial Infertility (COMPI) Research Program were included (Schmidt 2006). For basic (socio-) demographic variables, the 2010 version of the Demographic Standards provided by the German Federal Statistics Office were used as a reference (Hoffmeyer-Slotnik et al. 2010). The questionnaire also includes several new items that had to be developed for the specific purpose of this study.

One important goal was to gain insights into both partners' perspectives on most questions. Therefore gender-specific questionnaires were designed. Additionally, this reduces the risk of losing a couple completely for the sample if one partner is not willing to participate. Questionnaires for both sexes contain the same modules. Male respondents were not asked some specific questions for female respondents (e.g. question on abortions). For all questions the wording was adapted to gender and in some cases items were changed.

The 22 pages of the questionnaires were printed duplex in A4 format. It was designed to be automatically scanned and converted into electronic format using document scanner and forms processing software (Scanner: Kodak i60, Kodak GmbH, Stuttgart, Germany; Software: ReadSoft Eyes & Hands Forms, Readsoft AG, Frankfurt/Main, Germany). All questionnaires were assigned an ID printed on all pages. This ID was unique for all study packages except for the packages containing both a German and a Turkish questionnaire for each partner. In these cases both questionnaires had the same ID, to be able to check for duplicates. The ID served several purposes. The first was to be able to identify couples in the data set (each couple shared all but the first digit of the ID). Secondly, the ID allowed us to assign each questionnaire to a specific fertility clinic, which was important for monitoring the fieldwork and to calculate clinic-specific response rates (cf. Section 6).

6 Response Rate

Overall between July 2012 and May 2013, 916 study packages or 1,832 questionnaires were handed out to patients in six fertility clinics. Questionnaires returned by the end of July 2013 were considered. By then, 567 questionnaires had been returned. Two questionnaires for men were discarded as neither had been completed. This left 565 cases in the final sample of which 323 were female and 242 were male respondents. Both partners of 234 couples participated. This implies that men mostly participated together with their female partners, while women were much more likely to participate without their partners. 19 study packages with questionnaires in both German and Turkish were handed out, of which nine were completed and returned. This included four female and five male questionnaires; among four couples both partners used the Turkish questionnaire. The total response rate was 31%. For women it was 35% and for men 27%. As in the pretest (Section 4), the response rate varied considerably among the

clinics, ranging from 26 to 45% per clinic (for an overview see table 2). These results will be discussed in terms of data quality in the remainder of the section.

Table 2: Fertility clinic-specific response rates of the baseline survey of the PinK Study

Fertility clinic	n (packages handed out)[1]	n (questionnaires handed out)	n (returned)	response rate
1	103	206	53	25.7
2	155	310	138	44.5
3	282	564	147	26.1
4	155	310	88	28.4
5	60	120	37	30.8
6	161	322	102	31.7
Total	916	1,832	565	30.8

[1] Each package includes two questionnaires.
Source: PinK Study, own calculations.

The overall response rate is lower than in the pretest and lower than originally expected. However, it has to be considered that the questionnaires covered very personal and sensitive issues. Additionally, a follow-up as is usually recommended to increase response rates was not feasible owing to the study design. The possibility to re-contact patients would have probably resulted in higher response rates.

Calculation of the response rate is based on the assumption that all members of the target population were reached during the distribution period. In the baseline survey of the PinK Study this would be 916 couples in all participating fertility centers, varying between 60 and 282 per clinic.[7] It is likely that the assumption that all members of the target population received a study package does not hold. The numbers of new patients per year communicated by the fertility clinics were in some cases many times higher than the number of study packages handed out, indicating that the staff at the clinics did not strictly adhere to the eligibility criteria and not all members of the study population were approached. Accordingly, the denominator of the response rate is too small. Additionally, study packages might have been used more than once, which means that they were kept in stock even though the staff was explicitly asked to discard study packages of non-respondents. If this happened, again, the denominator of the response rate would be too small. Reasons could be that handing out study packages was simply forgotten, that those responsible for handing out the study packages were on sick-leave or vacation and did not have a temporary replacement or that the staff responsible did not see all new patients that came to the clinic. On the other hand, if study packages were handed out to couples to which eligibility criteria did not apply, the denominator would be too high.[8]

Next, potential sources of bias in the final sample have to be discussed. There are some aspects of the recruiting processes in the fertility clinics, which might have resulted in bias. This is always the case when the eligibility criteria are not applied systematically. For example when patients were selected based on eligibility criteria and on additional criteria, e.g., based on their presumed capability to read and understand either the German or Turkish study materials. If this is the case those groups would be underrepresented in our sample. It would also be problematic if the staff at the clinics did not approach certain groups of patients. This could be patients they perceived as emotionally overwrought, as supposedly not interested, or more generally, patients that they were afraid of losing

[7] The number was arrived at by subtracting the number of leftover questionnaires from the total number of study packages handed out to the fertility clinics during the distribution period.

[8] This would also result in a sample less homogenous than planned. See Section 7.3 for results of an analysis of the proper application of eligibility criteria with a focus on the correct timing.

as customers if bothered with our study. Many of the aspects described above strongly depend on the behavior of the staff at the clinics and consequently there might be systematic variation between fertility clinics.

Moreover, there are factors on the part of the potential respondents. Lynn (2008: 41) mentions several reasons for unit nonresponse in postal surveys that might also apply in this case: conscious refusal, forgetting to complete and/or to send back the questionnaire, inability to read and understand the language of the questionnaire, illness, or return envelopes getting lost in the mail. In the case of the PinK Study conscious refusal might have aroused from the fact that the questionnaire covered some rather sensitive issues, e.g., inquiring about stress in different life domains, partnership quality, abortions, treatment history, etc.. Patients or couples who felt stressed (in general or because of treatment) or were in a bad state of health when they received the questionnaire might have decided not to participate. Accordingly, these groups would be underrepresented in the sample. Other factors influencing the probability of conscious refusal in self-administered questionnaires are aspects of study design, such as topic of the study, presentation of the study materials, length of the questionnaire and presentation of the questions might influence the patients' decisions to participate (de Leeuw/Hox 2008: 240). Study materials were carefully designed and the goals of study described, still it might not have appealed to some patients; some may still have found the questionnaire too long.

At the end of the questionnaire respondents were asked if they were willing to participate in a follow-up study. 51% (n=293) of all respondents provided their contact information. Of those, 180 were women and 113 were men. In 96 couples both partners provided contact information.

7 Final Data Set

In order to ease data analysis the raw data resulting from scanning the questionnaires had to be further processed. Section 7.1 describes the process of data handling and editing and the computation of basic socio-demographic variables. In Section 7.2 the composition of the final sample is described based on these variables. Finally, in Section 6 the question came up if the eligibility criteria were properly applied by the staff at the clinics. In Section 7.3. we present results of an analysis investigating the proper application of the eligibility criterium concerning patients stage in the process of fertility treatment in the final data set.

7.1 Data Handling and Editing

Data processing was done in SPSS 20 (IBM Corp. Released 2011, IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). During the process, the researcher returned to the original questionnaires if necessary. As the questions asked in female and male questionnaires differed somewhat, separate data sets for women and men were produced. Later, these data sets were combined, after question and item numbers were standardized based on the female questionnaire.

Two data sets were produced. The first data set is in long format. It covers all individual respondents participating in the study, i.e., it includes one row for each respondent (n=565). The second data set contains only couples and is organized in wide format, i.e., it includes one row for each couple (n=234).

Data editing consisted of the following main steps:

- Defining missing values
- Checking value ranges
- Checking filters
- Coding open answers
- Computing basic variables

For all variables three different missing codes (87, 88 and 89) were defined, allowing each researcher to decide how to handle different missing types. Code 87 'no answer' was assigned for item non-response (respondents did not provide a (valid) answer to a question). Code 88 'don't know' was only assigned if a respondent checked the respective box in the questionnaire.[9] Code 89 'does not apply' was assigned if a respondent was filtered over a sub-question.

To check the value ranges, the actual values in the data set were compared with the possible values from the questionnaire. Problematic cases were identified and double-checked. If problems could not be resolved code 87 was applied. A peculiarity in self-administered questionnaires is that respondents sometimes check more than one box although they should only check one. When scanning the questionnaires, a double code was assigned, which consisted of the numbers of both boxes checked by the respondent. Checking value ranges included the identification of such cases in the data set. Double codes on questions with scales were resolved according to the following rules: 1. If boxes checked were next to each other on the scale, the case was coded .5 (e.g. the double code 23 was recoded to 2.5). 2. If boxes were not next to each other on the answer scale (e.g. 13), the respondent's answer was set to missing code 87. 3. If two boxes were checked and one was 'don't know' or 'doesn't apply to me,' the box checked on the scale was used, assuming that substantial information was provided. For double codes on other questions, e.g. if a respondent answered both 'yes' and 'no,' the respondent's answer was set to 87 if the problem could not be resolved by a check with the original questionnaire.

Filter questions consist of a main-question, which typically involves 'yes' and 'no' as answer categories, and one or more sub-questions, normally following a 'yes' answer. If a person didn't answer the main-question but answered the sub-question(s), the value leading to the sub-question(s) was applied to the main the question. If information on the main and sub-question(s) were contradictory, this was resolved by applying 87 to the main and sub-question(s).

Several questions provided open answer categories. Open answers were compared with the list of categories from the original questions. They were recoded into an existing answer category if appropriate. In that case the item indicating the open answer was unchecked if the text contained no further information. Generally, all open answers are included in the data set as string variables to allow for further analysis.

In a final step several variables were computed, which were supposed to be of use to all researchers involved in the study. For the generated variables a missing code was applied if the information necessary to compute the variable was incomplete. The wording of questions and answer categories on which the construction of the variables is based are available in Appendix 10.3.

Age: 5-year age groups were generated representing the age at the date of filling in the questionnaire (for categories and distribution see table 3).

[9] 'Dont know' as an answer category in the questionnaire was used a) for questions from other studies, if this answer category existed in the original study, b) if this category was of substantial interest, or c) if it was perceived that providing this option would reduce respondent burden.

Migration status: The variable reports the respondent's migration background, differentiating between 'no migration background,' 'first-generation migrant' and 'second-generation migrant.' It is based mainly on information from two corresponding questions about the country of birth of the respondent and the countries of birth of both parents, which have been adapted from the German Microcensus questionnaire (Statistische Ämter des Bundes und der Länder 2011). First-generation migrants are themselves born abroad, second-generation migrants were born in Germany but their parents were born abroad. For a few cases, additional information from a question on the respondent's native language was taken into account, which was the case for respondents born in Germany where one parent was born in Germany and information on the other parent was missing. If the respondent reported German as his native language, the respondent was treated as without migration background. Three respondents born abroad with both parents born in Germany and German as native language were coded as 'no migration background,' because of the restricted information that we have it cannot be ruled out that these are children of ethnic Germans ('Aussiedler'), which should be treated as with migration background.

Parity: This variable reports the number of biological children of the respondent. Since there were only five cases with three or more children, this information was combined in one category.

Relationship status: This variable reports if the respondent was married to his/her current partner at the time of filling in the questionnaire.

Insurance coverage: This variable indicates the respondent's insurance coverage, differentiating between 'statutory,' 'private' and 'Federal Armed Forces.' The categories 'statutory' vs. 'private' are based on two questions from the GEDA questionnaire (Robert Koch Institute 2012b). Firstly, respondents were asked if they had one of the following types of statutory insurance coverage together with a list of all six types of providers and an open answer category. Secondly, they were asked if they had private insurance coverage (except supplementary private insurance), with answer categories 'no,' 'yes' and 'I don't know.' In most cases answers were unambiguous. If statutory and private coverage were indicated statutory was applied, as this was asked first and the private insurance question could be potentially misunderstood as including supplementary insurance. 'Federal Armed Forces' applied if respondents specified this in the open answer category of the statutory insurance questions and in one case where the respondent did not provide any information on either question but mentioned in the question on current job that he/she was a soldier at the time of interview.

Level of education: The variable is coded according to the International Standard Classification of Education (ISCED-97) as it is applied for the German Microcensus (Schroedter et al. 2006; for categories and distribution see table 3).

Labor force status: This variable reports the respondent's labor force status. It is based on a question on the current activities of the respondent, which was adopted from the pairfam partner questionnaire of the first wave (pairfam 2013). The question includes a list of educational activities, work-related activities and non-work activities (multiple answers allowed). This demands a two-step procedure to generate the major labor force activity. This procedure is described in detail in the pairfam Data Manual (Brüderl et al. 2013) and was adhered to strictly. Firstly, the primary and secondary activities were derived from the possibly multiple activities. If more than one activity was stated, dominance rules were applied to generate primary and secondary activity status. In a second step, these variables were used to generate the labor force status variable: If only one of the statuses was an employment activity this was taken, if primary and secondary activity status were employment activities, the primary activity status was used, if no employment was mentioned then primary activity status was applied. For a full list of the categories of the final variable see table 3. Some categories of the original variable as

provided in pairfam contained no or very few cases. Therefore the non-working categories parental leave, voluntary year of social service, (early) retirement/occupational disability and other non-work activity were combined into the category 'nw- other' and the working categories part-time employment and marginal employment were combined in to the category 'w- part-time/marginal employment.'

Municipality size class: This variable is based on a question from the GEDA questionnaire (Robert Koch-Institute 2012b), which asks about the number of inhabitants of the town where they lived at the time of the interview (for categories and distribution see table 3).

7.2 Description of the Sample

Table 3 shows a description of the sample according to basic socio-demographic variables. The focus here is on individual women and men (more detailed analyses of couples will be published elsewhere). Still, one has to keep in mind, that 72.5% of the women and 96.7% of the men in the data set are part of a couple. Therefore, the samples of women and men are not independent. For some variables which should be identical for both partners in most couples, e.g. parity, relationship status and municipality size classes, couple structure of the data results in rather similar distributions among the categories when men and women are compared.

There is considerable variation in the distribution among age groups between women and men, even though the modal age group for both sexes is '30 to 34 years' of age. On average, men are older and the age span is far larger than for women. Approximately 7% of all men are older than 44, but none of the women. Of all women, 23% are under 30 years of age, of which 5 are even under the minimum age of 25 at which women are eligible for reimbursement in the statutory health insurance (cf. Section 2). The mean age for women is 32.8 (range: 22-44 years; SD=4.4) and for men 36.2 (range: 23-62 years; SD=5.9).

24% of women and 22% of men have a migration background. For women and men about 14% are first-generation migrants and about 9% are second-generation migrants whose parents were born abroad. The majority of the respondents were childless when they completed the questionaire (women: 85%; men: 84.6%), which implies that they did not have any biological children when they first consulted a fertility clinic. Similarly, most female and male respondents were legally married at that time (women: 83%; men: 88%). More men (20%) than women (12%) have private health insurance. For women the distribution equals that of the general population, men with private insurance coverage are overrepresented in the sample compared to the general population (cf. Section 2). There is a small minority of employees of the Federal Armed Forces for women and men.

Table 3: Socio-demographic characteristics of the PinK study population

	Women		Men	
	N	%[1]	N	%[1]
Total	323		242	
Age				
‹25	5	1.6	1	0.4
25-29	70	21.7	24	10.1
30-34	131	40.9	78	32.9
35-39	90	28.1	71	30.0
40-44	24	7.5	46	19.4
45-49	0	0.0	12	5.1
›=50	0	0.0	5	2.1
Missing information[2]	3	0.9	5	2.1
Migration status				
No migration background	243	76.2	183	77.9
First generation migrant	46	14.4	31	13.2
Second generation migrant	30	9.4	21	8.9
Missing information[2]	4	1.2	7	2.9
Parity				
0	273	85.0	204	84.6
1	42	13.1	30	12.4
2	4	1.2	4	1.7
3+	2	0.6	3	1.2
Missing information[2]	2	0.6	1	0.4
Relationship status				
Married	266	82.6	212	88.0
Not married	56	17.4	29	12.0
Missing information[2]	1	0.3	1	0.4
Insurance coverage				
Statutory	282	87.6	191	79.3
Private	39	12.1	48	19.9
Federal Armed Forces (Bundeswehr)	1	0.3	2	0.8
Missing information[2]	1	0.3	1	0.4
Level of education				
ISCED 1 Primary education	0	0.0	1	0.4
ISCED 2 Lower secondary education	9	3.0	10	4.3
ISCED 3 Upper secondary education	103	33.9	79	34.1
ISCED 4 Post-secondary non-tertiary education	53	17.4	15	6.5
ISCED 5 First stage of tertiary education	131	43.1	116	50.0
ISCED 6 Second stage of tertiary education	8	2.6	11	4.7
Missing information[2]	19	5.9	10	4.1
Labor force status[3]				
nw, education	3	0.9	4	1.7
nw, unemployed	8	2.5	2	0.8
nw, homemaker	6	1.9	1	0.4
nw, other	5	1.6	2	0.8
w, self-employed	9	2.8	23	9.7
w, full-time/vocational training	228	71.5	200	84.4
w, part-time/marginal employment	55	17.2	3	1.3
w, other	5	1.6	2	0.8
Missing information[2]	4	1.2	5	2.1
Municipality size classes				
‹ 2,000 inhabitants	74	23.9	57	24.6
2,000 - 4,999 inhabitants	47	15.2	33	14.2
5,000 - 19,999 inhabitants	63	20.3	43	18.5
20,000 -‹ 99,999 inhabitants	57	18.4	45	19.4
›= 100,000 inhabitants	69	22.3	54	23.3
Missing information[2]	13	4.0	10	4.1

[1] Percentages based on cases with valid information.
[2] Percentage of cases with missing information based on all cases.
[3] nw=not working; w=working.
Source: PinK Study, own calculations.

There are no respondents with pre-primary education in the sample (ISCED 0). Overall, there are very few respondents in the two lowest categories (ISCED levels 1+2). The modal category for both sexes is the first stage of tertiary education (ISCED 5); however there are more men with tertiary education (ISCED levels 5+6) than women. Concerning labor force status, table 4 shows that most respondents are working full-time (or are in vocational training). As is typical for Germany, more women than men are not working (6.9% for women compared with 3.7% for men) and more women than men work part-time or less (17.2% for women compared with 1.3% for men). Respondents are rather equally distributed among the municipality size classes.

7.3 Evaluation of the application of eligibility criterium concerning correct timing in the study population

In Section 6 'eligibility criteria not employed strictly' is identified as one potential problem of the data. To check if the respondents actually met the eligibility criteria as formulated in Section 3, an analysis was performed with a focus on the timing criterion in order to hold the patients' stage in the process of fertility treatment constant. Analysis resulted in a filter variable that should be used for sensitivity analysis, e.g. to inspect whether the distribution of a variable of interest depends on the patients' stage in the process of fertility treatment and, if this is the case, to decide on the relevant subsample for analysis. The filter variable classifies respondents as 'too early,' 'too late' or 'correctly timed' in the process of fertility treatment regarding the point in time defined in Section 3. A list of all questions on which the computation of the filter variable is based can be found in Appendix 10.4.

It is assumed that respondents identified as 'too early' received the study package before the patient briefing, e.g. at their first visit to the clinic for informative purposes. Categorization was based on three questions: Respondents classified as 'too early,' firstly did not mention that they had yet received a cost estimate (which is mostly handed out at the patient briefing), secondly, did not mention that they had any treatments recommended to them at the fertility clinic, and thirdly, did not mention having received diagnoses or had a former diagnosis confirmed at the clinic; the latter two indicating that examinations are not yet finished. 'Did not mention' indicates that the respondent answered 'no;' 'don't know' or did not answer all three questions. Overall 5.1% (n=29) of all respondents were classified as 'too early.'

Table 3: Classification of respondents according to correct application of the eligibility criterium concernig correct timing

	Women		Men		Total	
Category	N	%	N	%	N	%
Too early	14	4.3	15	6.2	29	5.1
Correct timing	277	85.8	200	82.6	477	84.4
Too late	32	9.9	27	11.1	59	10.4
6-11 months	19	5.9	18	7.4	37	6.5
12+ months	13	4	9	3.7	22	3.9

Source: PinK Study, own calculations.

Identification of those respondents 'too late' was based on the question whether a respondent had already started fertility treatment at the current clinic and if so, how many months ago he or she had started. Reference date is the date on which the patients

completed the questionnaire (one of the last questions in the questionnaire) since we have no information on the exact date on which the respondents actually received the study packages. Answers to this question revealed some variation: 37.6% of the male respondents (n=91) and 46.4% of the female respondents (n=150) answered that they had already started treatment, with a median duration of 3 months and 1 month respectively (range for women and men: 0 to 36 months).[10] Variation in median and mean duration was observed between fertility clinics (results not shown). This indicates - at least concerning the timing-criterion - that some fertility clinics adhered less strictly to the timing criterion than others. Since study packages were supposed to be handed out shortly before starting treatment, it is realistic that respondents had already started treatment at the current clinic at the date they completed the questionnaire. Durations of treatment of less than six months were not considered problematic.[11] This leaves 10.4% of the respondents classified as 'too late' of which 6.5% are between 6-11 months and 3.9% were 12 or more months 'too late.' In summary respondents classified as 'correctly timed' make up the main share.

8 Summary and Outlook

The PinK Study provides a wealth of new data on the situation of men, women and of couples who are about to start fertility treatment in Germany – a population that is not very well known in Germany. Even though sampling was regionally limited to RP and Wiesbaden (Hesse), it is believed that findings based on PinK data can be beneficial for understanding the situation in other federal states. One asset of the study is its interdisciplinary approach allowing for analysis of a wide range of research questions. Furthermore the data allow investigation not only of women, but also of men and couples, which implies that one does not have to rely on women's information as a proxy for the couple – as is often the case where the topic of (in)fertility is concerned.

Probability-based sampling was not feasible for a small and temporary target population as that in this study. Therefore the PinK Study was designed as a prospective cohort study in a clinical setting using self-administered questionnaires, which are particularly useful for highly sensitive topics such as that of the PinK Study. Overall 565 respondents participated in the study, resulting in a total response rate of 31% with considerable variation between clinics. This was lower than expected and to arrive at this number the period in which study packages were handed out at the clinics had to be extended and an additional fertility center was included in the study. Still, we must keep in mind that it is very likely that a considerable number of couples at the clinics to which eligibility criteria applied did not receive a study package, which implies that the denominator of the response rate is actually too small.

Recruiting respondents directly from the fertility clinics allowed us to apply eligibility criteria to arrive at a clearly defined and homogenous cohort of couples beginning fertility treatment. Analysis showed that the eligibility criteria concerning the stage of the patient in the process of treatment apply to almost 85% of all respondents; only 5% of all respondents have to be considered as 'too early' and 10 % as 'too late.' Unfortunately, we cannot rule out that other or additional criteria were applied by the staff at the clinics,

[10] 0 months indicates that the respondent started treatment less than a month before completing the questionnaire. Two women (0.6%) and one man (0.4%) did not answer the question. Assuming that there is no strong indication that they are in treatment too long, for the filter variable they are treated as timed correctly.

[11] For all respondents indicating how many months ago they had started treatment, this information was checked with the date of the first visit to a fertility clinic. Few respondents stated they started treatment more than one month before the first visit at a fertility clinic (n=7). It is suspected that they most likely misunderstood the question, which asked only about treatment in the current clinic, therefore it was decided not to treat them as 'too late' even if a duration of more than six months was stated (n=6).

which could result in over- and/or underrepesentation of different patient groups in the sample. Selectivity might also arise from patient behavior when patients decide to participate or not to participate in the study.

Due to the study design it is not possible to further quantify selectivity and therefore it remains unclear whether the sample realized is a good representation of the target population. Socio-demographic characteristics of the study population are not well known and to our knowledge no studies with a comparable design exist in Germany (this is especially true for male and couple data). We must conclude that the study design as such relied heavily on the cooperation of the fertility clinics. Compliance to the instructions was actually beyond the control of the research group, even though a great amount of time and effort was spent monitoring the field.

As the PinK Study is a prospective cohort study, a one-year follow-up study was started in July 2013. Since the respondents provided their contact information, study packages were sent by mail allowing us to send information letters in advance and to use reminders to increase response rates. The last reminders were in August 2014. The follow-up does not depend on the couples still being patients at fertility clinics. The follow-up study allows us to analyze what happened since the couples started fertility treatment. Combined with the baseline survey longitudinal analyses of individual and couple level causes and consequences of status changes (e.g. birth/abortion/discontinuation of treatment) can be performed.

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10 Appendix

10.1 Study materials

Cover sheet questionnaire

Bundesinstitut für Bevölkerungsforschung

UNIVERSITÄTSmedizin. Institut für Arbeits-, Sozial- und Umweltmedizin MAINZ

PinK

Paare in Kinderwunschbehandlung

Fragebogen

FÜR FRAUEN

Bitte füllen Sie den Fragebogen am Stück und ohne fremde Hilfe aus
und schicken Sie ihn im beigelegten frankierten DIN A4-Rückumschlag schnellstmöglich zurück an:

Universitätsmedizin
der Johannes Gutenberg-Universität Mainz
Institut für Arbeits-, Sozial- und Umweltmedizin
Obere Zahlbacher Straße 67
55131 Mainz

Für Rückfragen stehen wir Ihnen gerne zur Verfügung:
Tel: 06131-17 90 57 (Frau Becht)
Mo. - Do. von 10 bis 15 Uhr
E-Mail: pink@uni-mainz.de

Flyer

Ablauf der Befragung

Alle Kinderwunschzentren in Rheinland-Pfalz unterstützen die Umsetzung der PinK-Befragung, indem die Mitarbeiter dort die Unterlagen zur Befragung an alle Paare verteilen, die ein Kinderwunschzentrum aufgesucht haben und kurz vor ihrer ersten Behandlung stehen.

Die Fragebögen können kostenlos und anonym an das Institut für Arbeits-, Sozial- und Umweltmedizin gesendet werden. Es ist nicht möglich, die Fragebögen einer Person oder einem Paar zuzuordnen. Ihre Teilnahme an der Befragung ist unabhängig von Ihrer weiteren Behandlung und wird diese nicht beeinflussen.

Die Befragung wurde sowohl vom Datenschutzbeauftragten des Landes Rheinland-Pfalz und der Ethikkommission der Landesärztekammer Rheinland-Pfalz genehmigt.

Haben Sie Fragen?

Bitte kontaktieren Sie uns per E-Mail unter:
pink@uni-mainz.de
oder telefonisch unter:
06131 17-9057 (Mo. - Do., 10 - 15 Uhr)
am Institut für Arbeits-, Sozial- und Umweltmedizin der Universitätsmedizin Mainz

PinK
Paare in Kinderwunschbehandlung

Eine Befragung von

Bundesinstitut
für Bevölkerungsforschung

UNIVERSITÄTSmedizin.
Institut für Arbeits-, Sozial- und Umweltmedizin MAINZ

Was ist PinK?

PinK ist eine anonyme, schriftliche und freiwillige Befragung von Paaren in Kinderwunschbehandlung. Mithilfe von Fragebögen möchten wir besser verstehen, was Paare mit bisher unerfülltem Kinderwunsch bewegt und welche Themen sie beschäftigen.

Mit der Unterstützung aller Kinderwunschzentren in Rheinland-Pfalz möchten wir mit unseren Fragebögen möglichst alle Paare erreichen, die vor dem Beginn einer Behandlung stehen.

Ist das bei Ihnen der Fall? Dann möchten wir Sie herzlich bitten, an der Befragung teilzunehmen. Sie erhalten vor Ort vom Personal Ihres Kinderwunschzentrums den Fragebogen mit einem Informationsschreiben. Gerne können Sie sich mit weiteren Fragen direkt an uns wenden.

Worum geht es?

Im Mittelpunkt der Befragung steht die Situation von Paaren mit einem bislang unerfüllten Kinderwunsch. Wir möchten gerne etwas über ihren Weg zur Behandlung im Kinderwunschzentrum erfahren und Anlässe, die eine Behandlung begünstigen, ebenso wie Probleme und Barrieren kennenlernen.

Mit diesen Informationen können Paare mit unerfülltem Kinderwunsch künftig besser unterstützt und mögliche Hürden auf dem Weg zur Erfüllung ihres Kinderwunsches abgebaut werden.

Wer sind wir?

PinK wird gemeinsam vom Bundesinstitut für Bevölkerungsforschung und dem Institut für Arbeits-, Sozial- und Umweltmedizin der Universitätsmedizin Mainz durchgeführt.

Das Bundesinstitut für Bevölkerungsforschung (BiB) betreibt an seinem Sitz in Wiesbaden Forschung zu Bevölkerungsfragen und dem demografischen Wandel. Darüber hinaus ist das BiB auch für die Bundesregierung und die Ministerien beratend tätig und informiert die Öffentlichkeit. Mehr Informationen erhalten Sie unter: www.bib-demografie.de

Das Institut für Arbeits-, Sozial- und Umweltmedizin ist Teil der Universitätsmedizin Mainz und erforscht Zusammenhänge zwischen der Arbeitswelt, der Umwelt sowie dem gesellschaftlichen Umfeld und der Gesundheit des Einzelnen. Darüber hinaus unterrichtet das Institut Medizinstudenten in diesen Zusammenhängen. Mehr Informationen erhalten Sie unter: www.unimedizin-mainz.de/asu

Bundesinstitut für Bevölkerungsforschung

UNIVERSITÄTSmedizin. Institut für Arbeits-, Sozial- und Umweltmedizin MAINZ

PinK

Paare in Kinderwunschbehandlung

Was ist PinK?

PinK ist eine wissenschaftliche Befragung zum Thema „Kinderwunschbehandlung". Sie wird in allen Kinderwunschzentren in Rheinland-Pfalz von Forschern des Bundesinstituts für Bevölkerungsforschung und der Universitätsmedizin Mainz durchgeführt.

Worum geht es?

Im Mittelpunkt der Befragung steht die Situation von Paaren mit bislang unerfülltem Kinderwunsch. Mögliche Hürden und Probleme auf dem Weg ins Kinderwunschzentrum sollen ebenso identifiziert werden wie die Anlässe, die die Aufnahme einer Behandlung begünstigt haben. Dadurch wollen wir Paare unterstützen, die Chancen und Risiken einer Behandlung besser zu erkennen.

Dafür brauchen wir Ihre Hilfe!

Sie haben den Weg ins Kinderwunschzentrum gefunden und stehen möglicherweise am Anfang der Behandlung? Dann unterstützen Sie uns bitte durch Ihre Teilnahme.

Das Praxispersonal wird Ihnen gerne den Fragebogen und Informationsmaterial übergeben!

Haben Sie Fragen?

Informationen zur Befragung bekommen Sie unter
pink@uni-mainz.de oder Tel.: 06131 17-9057
Mo. - Do. von 10 bis 15 Uhr

10.2 Pretest questions analyzed in Section 4

Please note that questions were translated solely for informative purposes and to aid comprehension of analyses performed above.

German	English	Source of the question
Wie interessant fanden Sie persönlich das Thema des Fragebogens? 1 – Überhaupt nicht interessant 2 3 4 5 – Sehr interessant	How interesting was the topic of the questionnaire to you personally? 1 – Not at all interesting 2 3 4 5 – Very interesting	PinK Study
Wie finden Sie die Länge des Fragebogens? Viel zu kurz Etwas zu kurz Genau richtig Etwas zu lang Viel zu lang	What do you think of the length of the questionnaire? Much too short A bit too short Just right A bit too long Much too long	PinK Study
Persönlicher Code Bitte füllen Sie den folgenden persönlichen Code aus. Dieser Code dient in der geplanten Studie ausschließlich dazu, Fragebögen einer möglichen Folgebefragung einander zuordnen zu können, ohne auf eine Person schließen zu können. In dieser Vorstudie wollen wir nur ermitteln, ob der Code für Sie verständlich und für diese Zwecke geeignet ist. Ihr erstellter Code wird in keiner Weise weiter verwendet werden. Bitte tragen Sie in das nebenstehende Feld Ihre persönliche ID ein. Ihre ID wird wie folgt ermittelt: 1. Die ersten beiden Buchstaben Ihres Geburtsortes (z. B. Frankfurt) 2. Die Tagesangabe Ihres Geburtstags (z. B. 10.03.1985). 3. Die ersten beiden Buchstaben des ersten Vornamens Ihrer Mutter (z. B. Susanne).	**Personal code** Please fill in the following personal code. In the planned study, this code serves solely to allocate questionnaires from a possible follow-up survey to this one, but not to you personally. In this pretest, we only wish to learn whether the code is understandable to you and suitable for this purpose. The code you create will not be used for any other purpose. Please enter your personal ID in the following field. Your ID is created as follows: 1.The first two letters of your town of birth (e.g. Frankfurt) 2. Your day of birth (e.g. 03/10/1985) 3. The first two letters of your mother's first name (e.g. Susanne).	PinK Study

4. Die ersten beiden Buchstaben Ihres ersten Vornamens (z.B Mareike) 5. Die letzten beiden Buchstaben Ihres Nachnamens bei Geburt (z.B. Müller) Beispiel: F r 1 0 S u M a e r Ihr persönlicher Code: — — — — — — — — — —	4. The first two letters of your own first name (e.g. Mareike) 5. The last two letters of your last name at birth (e.g. Müller) Example: F r 1 0 S u M a e r Your personal code: — — — — — — — — — —	
Hatten Sie Schwierigkeiten bei dem Ausfüllen des persönlichen Codes? Ja und zwar _____ Nein	Did you have any trouble filling in your personal code? Yes, I had trouble with _____ No	PinK Study

10.3 Questions about socio-demographic variables analyzed in Section 7.2

Please note that questions were translated solely for informative purposes and to aid comprehension of analyses performed above.

Category	German	English
Age	Wie alt sind Sie heute?	How old are you today?
	Ich bin _ _ Jahre alt	I am _ _ years old
Migration Status	In welchem Land sind Sie geboren? Bitte benennen Sie das Land.	In what country were you born? Please name the country.
	Bundesrepublik Deutschland Ehemalige DDR In einem anderen Land und zwar: _____	Federal Republic of Germany Former GDR In another country (enter name): _____
	Wann sind Sie auf das heutige Gebiet der Bundesrepublik Deutschland zugezogen (zurückgekehrt)?	When did you move (return) to the current territory of the Federal Republic of Germany?
	Ich wohne nicht in Deutschland. Ich bin (zuletzt) im Jahr _ _ _ _ nach Deutschland gezogen.	I do not live in Germany. I moved (most recently) to Germany in the year _ _ _ _.
Parity	Haben oder hatten Sie persönlich leibliche Kinder?	Do you have or have you ever had your own biological children?
	Nein Ja Wenn ja, wie viele leibliche Kinder haben Sie? _ _ Kinder	No Yes If yes, how many biological children have you had? _ _ children
Relationship status	Sind Sie und Ihr aktueller Partner verheiratet? Wenn ja, seit wann?	Are you and your current partner married? If so, how long have you been married?
	Nein Ja, seit _ _ (Monat) und _ _ _ _ (Jahr) Weiß nicht	No Yes, for _ _ (month/s) and _ _ _ _ (year/s) I don't know

Insurance	Sind Sie bei einer der folgenden gesetzlichen Krankenkassen versichert?	Are you insured with one of the following statutory health insurance funds?
	Nicht gesetzlich versichert	I do not have statutory health insurance.
	AOK oder allgemeine Ortskrankenkasse	AOK or allgemeine Ortskrankenkasse
	Ersatzkasse, wie z. B. Barmer, Technikerkasse, DAK, KKH	Ersatzkasse, such as Barmer, Technikerkasse, DAK, KKH
	Betriebskrankenkasse oder BKK	Betriebskrankenkasse or BKK
	Innungskrankenkasse oder IKK	Innungskrankenkasse or IKK
	See-Krankenkasse oder Knappschaft	See-Krankenkasse or Knappschaft
	Landwirtschaftliche Krankenkasse	Landwirtschaftliche Krankenkasse
	Andere, und zwar: _____	Other insurance (please name): _____
	Weiß nicht	I don't know
	Sind Sie privat krankenversichert? *Hinweis: Private Zusatzversicherungen sind hiermit nicht gemeint!*	Do you have private health insurance? *Note: Not including supplementary private insurance!*
	Nein	No
	Ja	Yes
	Weiß nicht	I don't know
Level of education (ISCED)	Welchen höchsten Bildungsabschluss haben Sie erreicht?	What is the highest level of school education you attained?
	Von der Schule abgegangen, ohne Abschluss	Left school without a certificate
	Noch Schüler	Still go to school
	Haupt-/ Volksschulabschluss bzw. Polytechnische Oberschule mit Abschluss der 8. oder 9. Klasse	Secondary general school leaving certificate
	Mittlere Reife, Realschulabschluss bzw. Polytechnische Oberschule mit Abschluss der 10. Klasse	Intermediate school leaving certificate (Realschule, Mittlere Reife) or school leaving certificate from medium-level secondary school (Polythechnische Oberschule 10th grade)
	Fachhochschulreife	Entrance qualification for universities of applied sciences (Fachoberschule)
	Allgemeine oder fachgebundene Hochschulreife (Abitur)	General or subject-specific university entrance qualification
	Anderer Schulabschluss: _____	Other school leaving certificate: _____
	Weiß nicht	I don't know

Level of education (ISCED)	Welchen höchsten beruflichen Ausbildungsabschluss haben Sie?	What kind of vocational degree did you complete?
	Kein beruflicher Ausbildungsabschluss	No vocational degree
	Noch in Ausbildung	Still in vocational training
	Abschluss einer Anlernausbildung	Semiskilled training
	Abschluss einer Lehre oder gleichwertiger Berufsfachschulabschluss	Apprenticeship or equivalent degree
	Berufliches Praktikum	Practical Training ('Berufliches Praktikum')
	Meister-/Techniker- oder gleichwertiger Fachschulabschluss	certified master craftsman/ certified technician or equivalent degree
	Fachhochschulabschluss	University of applied science
	Hochschulabschluss ohne Promotion	University degree without doctorate
	Hochschulabschluss mit Promotion	University degree with doctorate
	Anderer beruflicher Ausbildungs-abschluss, und zwar: _____	Other degree, namely: _____
	Weiß nicht	I don't know
Labor Force Status	Was machen Sie zurzeit? Wenn mehrere Tätigkeiten auf Sie zutreffen, dann kreuzen Sie bitte alle an.	Which descriptions fits your current education and employment situation? You can pick multiple answers.
	Abendschule, Kolleg, 2. Bildungsweg	Evening school, working on a school-leaving certificate for adults
	Berufliche Ausbildung (Ausbildung/ Lehre/Berufsfachschule oder Handelsschule u.a.	Vocational training / apprenticeship
	Umschulung/Weiterbildung	Vocational retraining / continuing education
	Berufsakademie	University of cooperative education
	Fachhochschule, Hochschule, Universität	University of applied sciences, college, university
	Berufsvorbereitende Maßnahmen	Pre-vocational training
	Fachschulen (z. B. Meister-, Technikerschule)	Technical/professional school (e.g., certified master craftsman, certified technician)
	Sonstige Ausbildung	Other education
	Voll erwerbstätig	Full-time employment
	Selbstständig	Self-employment
	Teilzeitbeschäftigt (auch bei parallelen Teilzeittätigkeiten)	Part-time employment (also multiple part-time jobs)
	Praktika, Trainee, Volontariat o.ä. (auch unbezahlt)	Internship, trainee, work experience etc. (including unpaid work)

	Geringfügig erwerbstätig, Mini-Job, „Ein-Euro-Job“ (bei Bezug von Arbeitslosengeld 2)	Marginal part-time employment, mini-job, 'Ein-Euro-Job' ('one-euro job,' when receiving unemployment benefits)
	Gelegentlich oder unregelmäßig beschäftigt	Occasionally or irregularly employed
	Sonstige Erwerbstätigkeit	Other type of job
	Mutterschafts-, Erziehungsurlaub, Elternzeit, oder sonstige Beurlaubung	Maternity or paternity leave or other leave of absence
	Freiwilliges soziales Jahr, Bundesfreiwilligendienst	Alternative civilian service, voluntary social service year
	Arbeitslos, arbeitssuchend	Unemployed, seeking employment
	Hausfrau/Hausmann	Housewife / househusband
	Vorruheständler, Rentner, berufsunfähig	Retired, occupational disability
	Sonstige, nicht erwerbstätig	Other, not employed
Municipality Class Size	Wie viele Einwohner hat der Ort, in dem Sie leben?	What is the number of inhabitants of the town you live in?
	unter 2.000 Einwohner	Less than 2,000 inhabitants
	unter 5.000 Einwohner	Less than 5,000 inhabitants
	unter 20.000 Einwohner	Less than 20,000 inhabitants
	unter 50.000 Einwohner	Less than 50,000 inhabitants
	unter 100.000 Einwohner	Less than 100,000 inhabitants
	unter 500.000 Einwohner	Less than 500,000 inhabitants
	500.000 und mehr Einwohner	500,000 and more inhabitants

10.4 Questions for sensitivity analysis analyzed in Section 7.3

Please note that questions were translated solely for informative purposes and to aid comprehension of analyses performed above.

Filter category	German	English
'Too early'	Liegt Ihnen der Kostenplan für den bevorstehenden Behandlungszyklus (Behandlung und Medikamente) vor?	Do you have a copy of the cost schedule for your upcoming treatment cycle (for treatments and medications)?
	Nein	No
	Ja	Yes
'Too early'	Welche Behandlung wurde Ihnen als Paar im aktuell besuchten Kinderwunschzentrum vorgeschlagen? (Mehrfachnennungen sind möglich.)	What kind of treatment was proposed for you as a couple in the fertility center you are currently going to? (Multiple responses allowed)
	Zyklusmonitoring	Cycle monitoring
	Hormonelle Stimulationstherapie	Hormonal stimulation therapy
	Intrauterine Insemination (IUI)	Intrauterine insemination (IUI)
	Fremdsperma-Insemination	Insemination of donor sperm
	In Vitro Fertilisation (IVF)	In vitro fertilization (IVF)
	Intra-Cytoplasmatische Sperma-Injektion (ICSI)	Intracytoplasmic sperm injection (ICSI)
	Blastozystentransfer	Blastocyst transfer
	Spermiengewinnung aus Nebenhoden oder Hoden (MESA und TESE)	Sperm extraction (MESA or TESE)
	Eizellspende	Egg donor
	Kryokonservierung (Einfrieren) von Spermien und Eizellen	Cryo-conservation (freezing) of sperm and eggs
	Präimplantationsdiagnostik	Pre-implantation diagnosis
	Psychologische Unterstützung	Psychological support
	Eine andere, und zwar: _____	Other, (please name): _____
	Es wurde noch keine Behandlung vorgeschlagen.	No treatments were proposed.
	Weiß nicht	I don't know

‘Too early’	Welche Diagnose wurde Ihnen und Ihrem Partner im aktuell besuchten Kinderwunschzentrum gestellt oder bestätigt? (Mehrfachnennungen sind möglich.)	What diagnosis did the fertility center you are currently going to make or confirm for you and your partner? (Multiple responses allowed)
	Hormonelle Ursache bei mir	Hormonal cause diagnosed in me
	Störungen der Eileiter	Problem with the fallopian tubes
	Störungen der Gebärmutter	Problem with the uterus
	Störungen des Gebärmutterhalses	Problem with the cervix
	Andere Diagnose bei mir, und zwar: _____	Other diagnosis in me (please name):_____
	Ohne fassbare Ursache	No causes found
	Ursache liegt (auch) beim Partner	Cause diagnosed in partner (as well)
	Weiß nicht	I don’t know
‘Too late’	Haben Sie im aktuell besuchten Kinderwunschzentrum bereits mit einer Behandlung zur Erfüllung des aktuellen Kinderwunsches begonnen?	Have you already begun fertility treatment at the fertility center you are currently going to?
	Nein	No
	Ja	Yes
	Wenn ja, vor wie vielen Monaten haben Sie begonnen? _ _	If yes, how many months ago did you begin treatment? _ _