

# BMJ Open A cross-sectional study on informed choice in the mammography screening programme in Germany (InEMa): a study protocol

Eva-Maria Berens,<sup>1</sup> Maren Reder,<sup>2</sup> Petra Kolip,<sup>2</sup> Jacob Spallek<sup>1</sup>

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<sup>1</sup>Department of Epidemiology and International Public Health, School of Public Health, Bielefeld University, Bielefeld, Germany

<sup>2</sup>Department of Prevention and Health Promotion, School of Public Health, Bielefeld University, Bielefeld, Germany

## Correspondence to

Eva-Maria Berens;  
eva-maria.berens@uni-bielefeld.de

## ABSTRACT

**Introduction:** Breast cancer is the most prevalent cancer among women. In Germany, women are invited to a population-based mammography screening programme for the first time at the age of 50. Since it is still discussed whether the benefits of mammography screening outweigh its harms, the concept of informed choice has gained importance. The objective of this cross-sectional study is to assess the proportion of informed choices in the mammography screening programme. A special focus is on the examination of the impact of Turkish migration background and educational level on informed choices.

**Methods and analysis:** The proportion of informed choices is evaluated in a cross-sectional study with 3-month follow-up for behavioural implementation of the screening intention. A randomly selected sample of 17 000 women aged 50 years living in Westphalia-Lippe, a region in the Federal State of North-Rhine Westphalia, is invited to participate in this study. To reach adequate numbers of Turkish women, all possibly Turkish women in the sample are identified through a name algorithm and contacted. The sample is drawn from women registered in the study area for which the registration offices consented to supply data for the study (88% of all towns/cities in the study region). Women identified through the Turkish name algorithm received all materials in German and Turkish. The primary outcome is informed choice. Data are collected on informed choice components (knowledge, attitude, decision/implementation) as well as on its possible determinants (eg, health behaviour, perceived behavioural control, subjective norms, invitation status, migration background and other demographic variables). Data are collected before the screening appointment and at 3 months follow-up.

**Ethics and dissemination:** The study was approved by the ethical committee of the Medical Faculty of Muenster University. Results will be published in a relevant scientific journal and communicated to respondents and relevant institutions.

## INTRODUCTION

Breast cancer is the most prevalent cancer among women in Europe<sup>1</sup> and in Germany.<sup>2</sup>

## Strengths and limitations of this study

- Women receive the questionnaire close to the time of receiving the official invitation letter. Thus, the knowledge questions will reflect the knowledge level at the time of the decision. Intention as well as its implementation will be observed.
- Women who intend to participate in mammography screening may be more likely to participate in the study as they are interested in the subject.
- Informed choice will be assessed among first-time invitees and can be followed-up throughout their screening history in future research.

Population-based breast cancer screening programmes have been implemented in many European countries in the past decades. In Germany, a nationwide mammography screening programme has been fully implemented since 2009.<sup>3</sup> Women aged 50–69 years are invited to have a free mammogram in a specialised centre every 2 years. Currently there are about 10 million eligible women in Germany.<sup>4</sup>

Mammography screening, like other screenings, has both advantages and disadvantages. The aims of the population-based mammography screening programmes are the reduction of mortality from breast cancer and improvement of recovery chances by early detection and treatment.<sup>5</sup> Mammography screening has also negative implications such as false-positive results, overdiagnosis and over-treatment. In addition, negative psychological outcomes such as anxiety or stress while waiting for the result also play an important role.<sup>6,7</sup>

As mammography screening affects healthy women informed choice is crucial. According to the European guidelines for quality assurance in mammography screening, every woman should know the benefits and risks of

screening and make her decision for or against participation.<sup>5</sup> An 'informed choice' is based on (1) sufficient knowledge, (2) personal attitudes and (3) an intention and actual behaviour in accordance with these attitudes.<sup>8</sup> Although the concept of informed choice competes with the goal of a high participation rate (at least 70% to assure quality and effectiveness of the screening),<sup>5</sup> the German Joint Federal Committee (Gemeinsamer Bundesausschuss) and the German Mammography Association (Kooperationsgemeinschaft Mammographie) highlight its importance.

Previous studies from various European countries on participation in mammography screening have mostly focused on general determining factors. Age, income, occupation, educational level, number of children, housing property, place of residence and geographic distance to the screening are among the factors that have been shown to have an influence on mammography screening participation.<sup>9–11</sup>

Women with migration background are less likely to participate in mammography screening than women of the respective autochthonous population in several European countries.<sup>12–18</sup> In Germany, however, no such difference could be found. In contrast, a slightly higher proportion of women of Turkish origin seem to participate in mammography screening, compared to women of all other origins (52% vs 49%).<sup>19</sup>

Studies on knowledge have identified poor knowledge levels on mammography screening by the women concerned. Gigerenzer *et al*<sup>20</sup> found, that only 1.5% of all women in Europe know the estimated reduction in breast cancer mortality through regular attendance of the screening. In Germany, women aged 44–63 tend to overestimate the benefits and underestimate the risks of mammography screening.<sup>21</sup> Age, educational level and living area influenced the level of knowledge.<sup>21</sup> In contrast, in the Netherlands 88% of the women aged 50 years make an informed choice to participate in mammography screening, showing sufficient knowledge (defined as 8 of 13 items answered correctly), a positive attitude and an intention to participate.<sup>22</sup>

The primary aim of the InEMa study is to assess the proportion of informed choice in the German population-based mammography screening programme. The secondary aim is to examine the following hypotheses:

- A. Turkish women make less informed choices than autochthonous women do.
- B. Women of lower educational level make less informed choices than women of higher educational level do.

## METHODS AND ANALYSIS

The study is designed as a cross-sectional study with follow-up for behavioural implementation of the screening intention investigating informed choice in women invited for the national population-based mammography screening programme for the first time.

## Study population and design

Women aged 50 years living in Westphalia-Lippe in the Federal State of North-Rhine Westphalia in Germany will be invited to participate in the study. Women from 88% of all towns and cities in the study area could be included in our database as the respective population registries provided complete data sets including address and date of birth for our survey in 2012. The first postal questionnaire will be sent to the women 1–2 months after their 50th birthday when they are also expected to receive their invitation to the mammography screening programme by the regional mammography organisation and thus have to make a choice for or against screening participation. The envelope comprises a cover letter, a consent form, study information, the questionnaire and a prepaid return-envelope. After the proposed screening appointment, participants will be sent a follow-up questionnaire (3 month after the first questionnaire, figure 1). This allows assessing intention before screening appointment as well as actual screening behaviour.

Data collection will be conducted between October 2013 and July 2014 (first questionnaire) and January and October 2014 (follow-up). The questionnaires will be sent to women born between August 1963 and May 1964. The sample comprises 15 561 (54% of women in the participating areas) month wise randomly selected women without Turkish migration background. Women with Turkish migration background will be oversampled and all 1789 women with Turkish migration background in the participating areas will be invited. Women with possible Turkish migration background will be identified by a name-based algorithm. As Turkish family names have a meaning in the Turkish language and are thus highly specific, this method allows identifying women of Turkish origin in data sets without any other migration-related variables such as place of birth or nationality.<sup>23–25</sup>

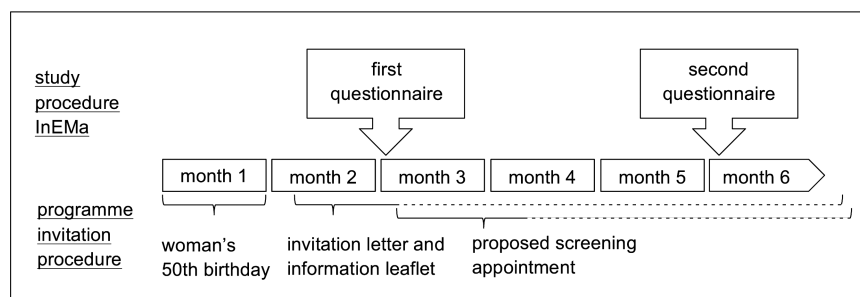
Women with a possible Turkish migration background will receive all materials in German and in Turkish. A bilingual reminder postcard will be sent to all women 1 week after the initial send-out. Women can choose between German and Turkish language for the follow-up questionnaire. Completed questionnaires and written consent for participation in our study will be returned by mail.

A pretest among 300 women showed that procedures are feasible. The questionnaire was adapted according to the results.

## Outcome measures

The primary outcome is informed choice. According to the following three dimensions, a decision is classified as informed or uninformed based on the classification model of Marteau *et al*<sup>8</sup>: knowledge (sufficient/insufficient), attitude (positive/negative) and intention/implementation (yes/no). An informed choice is defined as having sufficient knowledge and either having a positive attitude towards mammography screening being

**Figure 1** Timeline of mammography invitation and study procedure.



congruent with the intention to participate and implementation or having a negative attitude in congruence with no intention and implementation. A score of larger than three (possible score range 0–7) is categorised as having sufficient knowledge. Questions on knowledge were developed based on previous knowledge questionnaires of Mathieu *et al.*<sup>26</sup> and Marteau *et al.*<sup>8</sup> The attitude towards mammography screening is based on the Reasoned Action Approach.<sup>27</sup> A score of larger than or equal to zero (possible score range –8 to +8) will be categorised as positive attitude.

Further data will be collected about components and determinants of informed choice, like health behaviour, perceived behavioural control, subjective norms, invitation status, migration background and other demographic variables as described in [table 1](#).

### Statistical analysis

Data will be entered in a MS Access form and analysed using SPSS V.22.0 and MPlus. Five per cent of all questionnaires will be double-entered and data-entry quality will be reported.

Women who have been diagnosed with breast cancer will be excluded from the analyses. Women who already participated in the screening programme will be excluded as no intention to attend at the first contact can be assessed. Multiple imputation methods will be applied to handle missing data.

Descriptive analyses to characterise the study population and the proportion of informed choices and its dimensions (knowledge, attitude and intention/participation) will be performed stratified by educational level and (Turkish) migration background.

Univariate analyses, correlations ( $r^2$ ) and multivariate methods (multiple regressions, moderator and mediator analysis) will be performed to test the influence of educational level, (Turkish) migration status and other factors on informed choice and its dimensions. Further tests for differences in subgroups will be calculated (t test,  $\chi^2$  test). We will report results for single knowledge items to assess the possible influence of the type of question on the knowledge score. A non-responder analysis will be performed.

For the components of the questionnaire, item, reliability and factor analyses will be performed.

### Sample size

Given an expected difference of 10% in informed choice between subgroups, the study aims to recruit 5000 women to obtain a power of 0.80 with a confidence level of 95% with 20% exposed study participants (eg, low level of education, migration background). To reach adequate numbers of Turkish women, all Turkish women in the sample will be contacted.

### DISCUSSION

This study will provide estimates of informed choice for or against participation in the mammography screening programme in Germany among women invited for the first time. The findings will help to identify relevant subgroups with deficiencies in informed choices and other participation-related patterns.

There are various risks of bias associated with the study. We do not expect to have any selection bias as we drew a randomly selected sample of women from Westphalia-Lippe. However, it is expected that women who intend to participate in mammography screening are more likely to participate in the study as they are interested in the subject. It is also likely that the most deprived women such as low-literacy groups especially among migrants will not respond to the questionnaire. The proportion of migrants and low-literacy groups in our study will be compared to those from the general population (data from the statistical office). Recall-bias will be very low as women receive the questionnaire close to the time of receiving the official invitation letter and having to make the decision. The knowledge questions will reflect the knowledge level at the time of the decision which is a strength of our study.

An important goal of our research is to raise awareness for including informed choice as a standard concept in studies analysing participation in mammography screening. The InEMa study will contribute to this goal by providing the first empirical data about prevalence of informed choice and its determinants in Germany, and thereby help to further develop the biggest mammography screening programme in Europe.

### ETHICS AND DISSEMINATION

The study was approved by the ethical committee of the Medical Faculty of Muenster University and the Data

**Table 1** Collected data

Topics	Content of items	Type of items
Intention/decision	Intention to perform mammography screening in next 3 months, type of screening (program or elsewhere), intention to participate in next invitational period*	3 multiple choice items
Confidence	Confidence with the decision	1 item, 5-point Likert scale
Implementation of decision	Performance of mammography screening in last 3 months*	1 multiple choice item
Attitude	Important/not important, a good thing/a bad thing, beneficial/harmful, comfortable/uncomfortable	4 semantic differentials items, 5-point Likert scale, possible score range -8 to 8
Knowledge	Target population, frequency and meaning of a positive screening result, incidence and mortality with or without screening program, false-negative screening results and overtreatment	7 multiple choice items with one correct answer, possible score range 0 (very poor knowledge) to 7 (very good knowledge)
	Self-rated knowledge	1 item, 5-point Likert scale, ranging from 1 (very good) to 5 (very poor)
Health status	Self-rated health	1 item, 5-point Likert scale
Health behaviour	Smoking status, previous mammography performance, reason for previous mammography (screening or diagnostic), performance of manual breast self-examination, diagnostic mammography in last 3 months*	5 multiple choice items
Screening behaviour	Use of other screenings (gynaecological cancer detection, skin cancer detection and health check-up)	3 multiple choice items
Perceived behavioural control	Feelings and expectations towards mammography screening†	15 items, 5-point Likert scale
Role of others/ subjective norms	Advice to disadvice to participate or no advice by gynaecologist, general practitioner, partner, relatives and friends	5 items, 5-point Likert scale
Breast cancer	Self-rated breast cancer risk, familial history of breast cancer (mother or sister), own history of breast cancer	3 items, multiple choice and 5-point Likert scale
Demographic variables	Partnership, highest educational level, size of hometown, distance to screening unit, type of health insurance, registration for prevention bonus program of health insurance company	7 multiple choice items
Migration background	Country of birth, duration of stay, German nationality, language spoken at home	4 multiple choice items
German language skills	Skills in reading, writing, speaking and listening	4 items, 5-point Likert scale
Invitation status	Invitation for screening program received, time of receipt	2 items, multiple choice and free text
Influence of the questionnaire	Self-rated influence of questionnaire on decision	1 item, 5-point Likert scale

\*Second questionnaire only.

†First and second questionnaire.

Protection Officer of Bielefeld University. The second questionnaire contains an  $\alpha$ -numerical code to link the two surveys. Individual data (names and addresses) are stored separately from the questionnaire data. The questionnaire is not linked to the official invitation sent by the mammography screening organisation. Women have to give written consent to participate in the study.

We will publish the results on our main hypotheses as well as several exploratory papers. The comprehensive questionnaire developed and used in the study will be published with data on its reliability, validity and factorial structure of scales.

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**Competing interests** None.

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