# Investigating Barriers for Decision Making in a Danish Breast Cancer Screening Context

*Statistical Analysis Plan*

NCT05444725
Unique Protocol ID: 2016-051-000001, 2563

Date: August 23, 2022

# Statistical analysis plan

**Introduction**

Informed decision making and the use of decision aids are often recommended in breast cancer screening. However, informed decision making might be challenged by *ex ante* positive attitudes towards screening. Several studies have found high levels of enthusiasm towards screening including one of our own studies in a Danish breast cancer screening context (unpublished). Therefore, we will investigate preferences and attitudes towards breast cancer screening, invitation, and decision making among Danish women in this study. The study will be conducted by sending out an online questionnaire to women aged 44-49 in Denmark. Women will be randomized to one of three versions of the questionnaires: 1) Questionnaire with "Stage of Decision Making"-question to investigate women's decision making process regarding participation in screening (by asking whether women have made their decision about participation or not based on six different options of decision stages), 2) Questionnaire with choice framing (presentation of a choice between participation in breast cancer screening or no screening), or 3) Questionnaire with opportunity framing (only presentation of screening, no alternative) to investigate the decision making process and the impact of different framing. Next, women are asked to state their intended participation in screening on a 5-point Likert scale.
Subsequently, questionnaire data will be linked to register data on sociodemographic factors from Statistics Denmark.

The following variables are available:

- Register data: educational level, socioeconomic status (based on employment), civil status, municipality, and whether the person was immigrant, descendant (born in Denmark by foreign parents) or of Danish origin.
- Questionnaire: age, educational level, previous breast cancer, perceived risk of breast cancer, breast cancer worry, breast cancer among family/friends, previous mammogram, intended participation (and stage of decision making for one of three groups), reading health information in general, having read the leaflet about breast cancer screening (link in the invitation letter to this study), being more positive/negative about screening after having read breast cancer screening information, being more/less willing to participate after having read breast cancer screening information, indicating that screening participation is their very own decision vs. indicating that you should follow recommendations from health authorities about screening participation (two questions), indicating that they prefer to make their own decision about screening participation based on own attitudes and values and the information available vs. indicating that they prefer that health authorities recommend whether they should participate or not (two questions), and preferences for future screening invitation.

**Hypothesis and aims**

Main hypothesis: The majority of Danish women have made the decision about breast cancer screening participation prior to invitation and presentation of screening information. More specifically, the main hypothesis for this study is that 80% of Danish women have already made their decision when presented to the opportunity framing and 70% when presented to the choice framing.

To investigate the main hypothesis above, the following analyses will be performed, where subheadings indicate the theme addressed by the analyses:

*Screening decision made prior to reading information*

- Estimate prevalence of women who have made the decision to participate in breast cancer screening across randomization groups and for each of the two framings. Intended participation is answered on 5-point Likert scale and will be dichotomized as participation (two categories) and non-participation/unsure (three categories).
- Compare prevalence of women who have made the decision depending on opportunity vs. choice framing with chi-squared test.
- Crude and adjusted* logistic regression with intended participation as outcome and framing as independent categorical variable. The group receiving "Stage of decision making" is included in this analysis for comparison.
  Intended participation is answered on 5-point Likert scale and will be dichotomized as participation (two categories) and non-participation/unsure (three categories).
- Sensitivity analyses restricting intended participation to only one category for all analyses (only "Yes, I want to participate" and not "I think I want to participate").

*Stage of decision making*

- Estimate prevalence of women in each decision stage based on "Stage of decision making".
- Crude and adjusted* logistic regression with intended participation as outcome and "Stage of decision making" as independent continuous variable.

Aim 1: Women do not take the presented screening information into account when making their decision about participation.

To investigate aim 1, the following analyses will be performed, where subheadings indicate the theme addressed by the analyses:

*Different framing*

- Same analyses as for main hypothesis – does framing make a difference (and is information taken into account)?

*Do women read health information*

- Estimate prevalence of women who read health information in general and who have read the breast cancer screening information specifically.
- Crude and adjusted* logistic regression with participation as outcome and reading information (in general + screening related) as independent variables.

*More or less positive/negative after reading information*

- Estimate prevalence of women who are more or less positive/negative depending on previously intended participation and framing, respectively.

- Crude and adjusted* logistic regression with more or less positive/negative as outcome and intended participation and framing as categorical independent variables.
  Dichotomization of outcome depends on results**

*More or less willing to participate after reading information*

- Estimate prevalence of women who are more or less willing to participate depending on previously intended participation and framing, respectively.
- Crude and adjusted* logistic regression with more/less willing as outcome and intended participation and framing as categorical independent variables.
  Dichotomization of outcome depends on results**

Aim 2: Women think of the screening participation as less of an actual (individual) choice and more of something to comply with when invited.

To investigate aim 2, the following analyses will be performed:

- Estimate prevalence for each of the two statements (indicating that screening participation is their very own decision vs. indicating that you should follow recommendations from health authorities about screening participation) for all five categories (5-point Likert scale, “strongly agree” – “strongly disagree”).
- 2x2 table of seeing it as individual choice vs. recommendation to comply with ("strongly agree” and “agree” for both statements).
- Crude and adjusted* logistic regression with thoughts on screening participation as outcome and intended participation and framing as categorical independent variables.
  Thoughts on screening participation is a dichotomized variable based on the two statements mentioned above. Women are categorized as “individual choice” when they answer “agree” or “strongly agree” to the first statement and answer “neutral”, “disagree”, or “strongly disagree” to the other statement (coded 0). In contrast, women are categorized as ”recommendation to comply with” when they answer “agree” or “strongly agree” to the second statement and answer “neutral”, “disagree”, or “strongly disagree” to the other statement (coded 1). Inconsistent responses to the two statements and disagreement towards both statements are coded as missing and their frequency reported.

Aim 3: Women do not want to make an informed decision about their own health (and be responsible for their own health).

To investigate aim 3, the following analyses will be performed:

- Estimate prevalence for each of the two statements (indicating that they prefer to make their own decision about screening participation based on own attitudes and values and the information available vs. indicating that they prefer that health authorities recommend whether they should participate or not) for all five categories (5-point Likert scale, “strongly agree” – “strongly disagree”).
- 2x2 table of wanting informed decision making vs. health authorities make recommendation ("strongly agree” and “agree” for both statements).

- Crude and adjusted* logistic regression with preference for decision making as outcome and intended participation and framing as categorical independent variables.
  Preference for decision making is a dichotomized variable based on the two statements mentioned above. Women are categorized as “wanting informed decision making” when they answer “agree” or “strongly agree” to the first statement and answer “neutral”, “disagree”, or “strongly disagree” to the other statement (coded 0). In contrast, women are categorized as ”health authorities make recommendation” when they answer “agree” or “strongly agree” to the second statement and answer “neutral”, “disagree”, or “strongly disagree” to the other statement (coded 1). Inconsistent responses to the two statements and disagreement towards both statements are coded as missing and their frequency reported.

At the very end of the questionnaire, women are asked about their preferences for future screening invitation (how and what material is sent at invitation regarding invitation letter, information leaflet and pre-scheduled time for screening). For this question, four pre-defined options are suggested based on the current Danish invitation strategy and, lastly, a text field is provided for other suggestions and thoughts. Based on these responses, prevalences can be estimated for the four pre-defined invitation strategies. Next, responses provided in the text field can be investigated and possible themes and other strategies can be identified. This can be important knowledge for future research and administration of the Danish breast cancer screening program.

* The following variables are used as independent variables in adjusted analyses: educational level, socioeconomic status (based on employment), civil status, whether the person was immigrant, descendant (born in Denmark by foreign parents) or of Danish origin, perceived risk of breast cancer, breast cancer worry, and previous mammogram.

** Because women are generally very positive about screening and want to participate in screening, we hypothesize that it is more likely that women will be more negative and less willing to participate after reading screening information than becoming even more positive and more willing. This is because we assume that it is difficult to be much more positive and more willing to participate than is already the case.
If this hypothesis is true, the responses will be dichotomized as follows:
Positive/negative: Focus is on women being more negative, therefore, the two “negative” responses will be coded as 1 and the two “positive” responses and “unchanged” will be coded as 0.
More/less willing: Focus is on women being less willing to participate, therefore, the two “less willing” responses will be coded as 1 and the two “more willing” responses and “unchanged” will be coded as 0.
If our hypothesis is not true, the dichotomization will be reversed (“unchanged” will still be coded 0).