Randomised controlled trial protocol

ImmigrantScreen

"Creating a more equitable breast cancer screening program by approaching immigrant women in a familiar language"

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Date: February 2023

Revision history

Version number	Date
Version 0.1	January 2021
Version 0.2	February 2023

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Clinical study summary

Title:	ImmigrantScreen - Increasing access to breast cancer screening among immigrants
Study objectives:	Examine whether an invitation to breast screening in the language of origin influenced attendance.
Clinical study design:	Randomized controlled trial.
Inclusion / exclusion criteria:	**Inclusion criteria:** Female sex, screening age, birth country of Algeria, Egypt, Iraq, Lebanon, Morocco, Palestine, Pakistan, the Philippines, Poland, Somalia, Sudan, Syria, or Tunisia, representing the following languages: Arabic, English, Polish, Somali and Urdu. **Exclusion criteria:** Diagnosed breast cancer before invitation, missing information about birth country.
Primary performance endpoints:	Attendance
Secondary performance endpoints:	Attendance after primary invitation, attendance after a reminder, stratified by age and country of birth.
Safety endpoints:	Breach of privacy or a significant drop in attendance.
Duration of study:	Approximately one year for recruiting women and two years for running analyses and publications
Follow-up:	Not applicable

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1 Introduction

This two-armed, parallel group, blinded, pragmatic randomised controlled trial is designed to examine the potential superior effect on attendance when inviting immigrant women targeted BreastScreen Norway to mammographic screening in their presumed language of origin and in Norwegian versus in Norwegian only. The study is aimed at enrolling 14,000 immigrant women.

Breast cancer is the most common cancer among women in Norway and word-wide (1). In Norway, almost 3700 women were diagnosed with breast cancer and 600 died from the disease in 2017 (2). The national screening program for breast cancer, BreastScreen Norway, started in 1996 (3). The primary goal of the screening program is to reduce breast cancer mortality through early detection. The annual attendance rate in the program is about 75%, however immigrant women have a substantially lower attendance rate compared to non-immigrant women (4). A qualitative study have highlighted some of the barriers for immigrants to attend screening, among those were the invitation letter and language (5).

BreastScreen Norway and the Norwegian colorectal cancer screening program joined forces and applied for funding to investigate whether invitations to screening in a major language in invited immigrant's country of birth would increase attendance. The application successfully asked for funding for three studies: a randomized controlled trial (RCT) of inviting women to BreastScreen Norway in their language of origin, a similar RCT for the colorectal cancer screening program, and a qualitative study.

This protocol covers the first of the three studies proposed, in which we will perform an RCT to investigate whether receiving a translated version of the invitation letter and information leaflet ("invitation letter") in the official language of the country of birth ("official language") increases the attendance rate of immigrant women invited to BreastScreen Norway.

2 Study Description

2.1 Background

2.1.1 Breast cancer incidence, risk and survival

Breast cancer is the most common cancer among women in the world and in Norway (1). The lifetime risk of the disease is 8% and 5-years relative survival is 90% (2). Breast cancer mortality has decreased during the last decades and Norway has the lowest rates among all Nordic countries (6). Implementation of high-quality screening for women aged 50-69 years, and improved treatment are the reasons for this improvement (7).

2.1.2 Breast cancer in immigrant population groups in Norway

Today, 14% of the Norwegian population are immigrants, defined as residents of Norway having been born outside of Norway by two parents born outside of Norway (8). The Norwegian immigrant population is heterogeneous, due to the large variation in countries of origin as well as reasons for immigration. Breast cancer incidences vary widely between immigrant groups, reflecting the incidence in the countries of origin (9). The age-standardized breast cancer incidence is slightly higher in immigrants from Northern and Western Europe compared to non-immigrants, and lower in immigrants from Asia and Sub-Saharan Africa.

2.1.3 BreastScreen Norway

BreastScreen Norway invites all women aged 50-69 to two-view mammographic screening every two years (10). The aim of the screening program is to detect breast cancer in an early stage and thereby reduce the

treatment burden and mortality from the disease. The women are offered screening through a personal invitation letter in Norwegian (regular mail or digital mailbox), with stated time and place for the examination. Screening takes place at 30 mobile or stationary units distributed around the country. A reminder is sent to non-attending women 4–6 weeks after the originally scheduled appointment, offering the women an opportunity to schedule a new appointment by contacting the local breast center. Three in four women attend each screening round. Further assessment takes place at 17 breast centers, centrally located and distributed across all counties. About 3% of the women are recalled from screening for further assessment, while about 20% of the recalled women are diagnosed with breast cancer. The effects of mammographic screening, mainly on the reduction of breast cancer mortality and on overdiagnosis, have been discussed during the last decades. The International Agency for Research on Cancer (IARC) and other health authorities including the European Commission Initiative on Breast Cancer (ECIBC) consider the benefits to outweigh the harms and mammographic screening is offered to women in all continents (11-13).

2.1.4 Inequalities in cancer screening

Demographic characteristics are shown to vary between attendees and non-attendees in breast cancer screening (14). However, for colorectal cancer, contextual elements such as demographic characteristics and offered screening method differ between countries (15). Therefore, reasons for non-attendance may depend on factors such as region of origin. Poor adherence to screening recommendations among immigrants has been shown for breast and cervical cancer screening in Norway (4, 16). The uptake also varies between different immigrant and ethnic groups. A qualitative study from BreastScreen Norway identified several mediating factors of influence for attendance in a group of immigrants, such as examinator's gender, invitation letters, relatives, and religion (5).

2.1.5 Data on country of origin in the Cancer Registry of Norway

As a result of recent studies showing differences in breast cancer screening uptake between immigrant groups (4, 17), data from Statistics Norway about country of origin for immigrant citizens is now available in the Cancer Registry of Norway without consent from the individual. Further, country of origin is available to screening program planners, enabling language-targeted information. This gives a unique opportunity to study the effect of information about cancer screening given in the presumed maternal language of immigrant groups. In most parts of the world, cancer screening uptake is lower in socio-economically deprived groups, and in immigrants than the rest of the population (18, 19). A recent publication from BreastScreen Norway showed a substantially lower attendance rate among immigrants compared to non-immigrants, 56% versus 78% (4). Among Somali women, only 14% attended BreastSCreen Norway. Similar findings are shown for cervical cancer screening (16).

2.2 Study Rationale

The prerequisite for an effective cancer screening program is acceptance of the invitation. A goal is equally accessible cancer screening program to all women in the target group. According to the so-called Nordic welfare model, the entire population should have equal access to health care (20). This means that the discrepancy in attendance in screening between women born in Norway and women born abroad by foreign-born parents reduces the equity of the screening program. There are several barriers to attending breast cancer screening, and these can vary according to people's background. One known barrier to cancer screening is the lack of awareness and understanding of the screening invitation, which compromises the invitee's ability to make an informed choice about attending (21, 22). In BreastScreen Norway, the invitation letter and information leaflet are in Norwegian only. The most essential information is available in English on

the webpage of Cancer Registry of Norway. Lack of information in different languages might be of influence for the attendance rate (22). Ideally, all invitees to cancer screening should be offered information in a way which allows them to make an informed choice whether to attend or not. To ensure that invitation to cancer screening is an equitable health service for all, action should be taken to make sure that the invitation letter is understood by all invitees.

Sending invitation letters to screening in the official language of selected immigrants birth countries may signal to these immigrant resident groups that the health authorities care for them and are striving to reach them. Yet, the effect of sending invitations in immigrants presumed maternal language has not been investigated in Norway, and there is currently a lack of knowledge on how to increase attendance in BreastScreen Norway among immigrants. Most studies have been conducted outside Europe and the needs and type of information are constantly changing. A recent Norwegian trial has tested how to increase cervical screening uptake in immigrant women (23).

To advise the Norwegian health authorities about how to reach groups in need of adapted information on breast cancer screening and to contribute to fill knowledge gaps related to mammographic screening for immigrants, we will test the effect of translated information when inviting immigrant residents in Norway to BreastScreen Norway in their language of origin by conducting an RCT, comparing the attendance among immigrant receiving the invitation letter and the information leaflet in the presumed language of origin and Norwegian, versus Norwegian only.

3 Objectives and hypothesis

3.1 Objectives

3.1.1 Primary objective

To study the effect on attendance of inviting selected immigrant groups to BreastScreen Norway by translated invitation letter and information leaflet in the major official language of the woman's country of birth, in addition to Norwegian, versus in Norwegian only.

3.1.2 Secondary objective

To study whether the effect on attendance of inviting selected immigrant groups to BreastScreen Norway by translated invitation letters in the major official language of the woman's country of birth differs across country of birth – five language groups with a substantial number of women in the target group of the screening program will be selected. We will also stratify the outcome by age, screening history and residential time in Norway.

3.1.3 Other study objectives

We will study recall rates, cancer detection and characteristics of the tumor.

3.2 Hypothesis

We expect that immigrant women in the intervention group (major official language and Norwegian) will have a higher attendance rate compared to the control group (Norwegian only).

3.4 Risks and anticipated adverse events that are to be assessed

The risk of this study is that an invitation in the major official native language of the women's country of birth will lead to lower attendance.

4 Project methodology

We will run a randomized clinical trial (RCT) in five language groups, sending an invitation letter in a major official language in addition to Norwegian to a randomly assigned half of the women, while the other half will receive an invitation only in Norwegian according to normal procedures (randomization 1:1 within each language group). Attendance rates, attendance among the invited, in the two arms will be compared. Based on results of 2018 the study by Bhargava et al. we will include women born in Poland, the Philippines, Pakistan, Somalia, and Arabic speaking countries (Iraq, Syria, Lebanon and Palestine) (4). These women have a low attendance rate in BreastScreen Norway and the number of women in the target group is sufficient to detect a difference in attendance (see chapter 7.4 for minimal effect size detectable). Descendants of immigrants will not be included in the RCT. All information material, including the invitation letter, information leaflet, response letter, and invitation reminder, will be translated by a professional agency, quality assured by professionals and tested by health professionals and women in the target group. The translation work started in January 2020, while a pilot of the trial will be performed during the fall 2020. The RCT will start January 2021 and run for one year. Quality assurance will run throughout 2021. Results will be analysed, interpreted, and disseminated during 2023.

5 Study design

5.1 General

5.1.1 Description

We will perform a *randomized controlled trial*. The study has *two arms* to which women can be randomized – an intervention arm and a control arm. The intervention arm consists of five different *strata*: the Arabic stratum, the Filipino stratum, the Pakistani stratum, the Polish stratum, and the Somali stratum. As the randomization in this study is stratified, women are first divided into strata, and then randomly assigned to either the intervention or the control arm. The study has a *parallel group design*, meaning there are no crossovers between the two arms. The intervention arm will only get the intervention, and the control arm will never receive the intervention. As the study is *blinded*, women are de-identified before they are randomized and will remain pseudonymized to the researchers throughout the study period. The study is *pragmatic*, meaning it will be embedded within BreastScreen Norway, and data collection will take place in an everyday screening setting. In summary, this is a two-armed, parallel group, blinded and pragmatic randomized controlled trial.

5.1.2 Primary endpoint

The primary endpoint of this study is **attendance**, defined as the number of women attending a screening examination among the number of women invited to a screening examination during the study period. The study will compare attendance in the two groups.

5.1.3 Equipment, databases and systems

The equipment needed to perform this trial is the data system at the Cancer Registry of Norway with which the target population is defined, invited, and recorded in BreastScreen Norway. With this system, administrative employees from the Cancer Registry of Norway selects cohorts and groups of women to invite based on their place of residence in a standard setting. Women targeted by the screening program are identified through the National Population Register. The data system then automatically selects women with the longest time interval since the previous invitation. When women are selected, an invitation

number and an invitation is generated in the **invitation table**, with an automatically generated appointment. The invitation is sent in the form of a letter (physical or digital depending on the woman's preference for governmental communication), together with an information leaflet designed to guide the women to make an informed decision on whether to attend or not.

For this RCT, a **study table** will be created in the database of BreastScreen Norway. Whenever a woman is to be invited, the invitation system will check whether her personal identification number exists in the study table, and if it does, checks whether she is registered with a 0/1 for control/intervention group and what language she is to be invited in if in the intervention group (1 for Somali, 2 for Polish, 3 for English, 4 for Urdu, 5 for Arabic). When the women attend at the screening unit, they are interviewed, and imaged ("examination" hereafter) by radiographers. When the radiographer's registers data from this examination in a software connected to the database at the Cancer Registry of Norway, it is stored in the **attendance table**. Women are registered in the databases with a personal identification number, which makes it possible to merge all these tables into study tables for different projects.

5.2 Study intervention

5.2.1 Description

The intervention in this study is defined as sending a **physical invitation letter and an information leaflet (2 items) in the women's language of origin and Norwegian.** A physical reminder and a physical response letter are sent in the women's language of origin and in Norwegian. The language in the translated versions follows the strata and are as follows: Arabic in the Arabic stratum, English in the Filipino stratum, Polish in the Polish stratum, Somali in the Somali stratum, and Urdu in the Pakistani stratum. The translated versions of the letters are found in the appendix. The Arabic stratum includes women born in Algeria, Egypt, Iraq, Lebanon, Morocco, Palestine, Sudan, Syria, and Tunisia.

5.2.2 Comparator

The comparator in this study is defined as sending a **physical invitation letter and an information leaflet (2 items) in Norwegian.** A physical reminder and a physical response letter are sent in Norwegian. The comparator is the current standard of practice in BreastScreen Norway.

6 Risks and benefits

This study is not a clinical study, and as such, there no major expected risks to the participants. A risk analysis is therefore not performed.

6.1 Anticipated benefits

A more equitable breast cancer screening program, through higher attendance rates among immigrants and increased knowledge about the health care system in Norway among immigrants.

6.2 Anticipated risks

The risk with this study is that the direction of the effect estimate is opposite of our hypothesis – i.e., that fewer immigrant women attend the screening program. Attendance in the screening program must be based on a voluntary choice. This study is designed to increase equity in the program and provide immigrants with equal opportunities for access to health care. If our intervention further increases the gap between the general and the immigrant population, we will consider it an adverse event, which will lead to termination of the study. There can be many reasons for such an event, for instance confusion due to

neighbours, friends or family being randomised to receive invitations in another language than the participant. Furthermore, just because the participant is born in a country, does not mean they speak the language of that country. On the other hand, participants receiving invitations in their own language may feel a pressure to attend, which goes against the principle that attendance should be based on voluntary choice.

6.3 Data and Safety Monitoring Board

To avoid the adverse event described above, we will recruit an independent Data and Safety Monitoring Board (DSMB). A DSMB is an independent review board consisting of experienced researchers/trialists that monitor the data in the trial in order to ensure safety. The DSMB will review the data at 3 set time points: At the end of Q1, Q2, and Q3 in 2021. A dedicated research assistant managing the data at the Cancer Registry of Norway in accordance with the data management plan will send aggregate data to be reviewed by the board. If the data match the termination criteria defined in chapter 7, data collection in the study will stop. The sending of aggregate data circumvents the necessity of an ethical review board approval.

Safety and Monitoring Board		
Name	Position	Institution
Trude Robsahm	Researcher	Cancer Registry of Norway
Tone Hovda	Breast radiologist	Vestre Viken Health Trust
Jan F Nygård	Leader, dept. of registry informatics	Cancer Registry of Norway

7 Statistical considerations

7.1 Statistical design

This study will be designed a superiority trial with the difference in attendance rate between the study and control arm as primary outcome. . Bivariate tests will be used to analyze the primary outcome. In addition, effect estimate plots for the total effect and each specified subgroup will be made using rate ratios, corresponding 95% confidence intervals and p-values.

7.2 Trial participants and expected attendance

In total, we expect about 7400 women to be invited to the RCT, including 2200 women from Poland, 1400 from the Philippines, 1500 from Pakistan, 1300 from Arabic countries, and 500 from Somalia (Table X). Women within our five strata will be identified in the databases of BreastScreen Norway. These five strata represent the most common immigrant groups in the program. The different strata have different attendance rates, and we expect attendance rates in the control arms in the trial to be similar to those observed in 1996-2014.

Table 1. Target group 1996-2015 adapted from Bhargava et al 2018 (4), and estimated numbers for invited (total and each arm) and attended (control arm) in 2021

Country (language)	Target group 1996-2014 (n)	Expected to be invited in 2021 (n)	Attendance rate 1996-2014 (%)	Expected to attend in the control group 2021 (n)
Arabic	2600	1300 (650 in each arm)	40%	260
English	2700	1400 (700 in each arm)	54%	378
Polish	4300	2200 (1100 in each arm)	50%	550
Somali	1000	500 (250 in each arm)	14%	35
Urdu	3000	1500 (750 in each arm)	34%	255
Total	13 600	7400 (3700 in each arm)	40%	1480

Power calculations are performed for two independent sample proportions with a statistical power (1-β, where beta is the type II error rate) of 0.8 and significance level (α, type I error rate) of 0.05. To show that differences ≥10% is statistically significant for attendance rates in the control group given in Table X, at least 356 invitations need to be sent to women from Poland, 379 to women from the Philippines, 373 to women from Pakistan, 388 to women receiving invitation in Arabic and 241 to women from Somalia (Table 2). Estimated number of invitations and sample size needed in the study arm to show that a 10% increase in the study arm compared to the control arm is statistically significant.

Table 2: Estimated number of invitations in the study arm and sample sized needed in the study arm to reach statistically significant increase of 10% in attendance in the study arm (statistical power (1-β, where beta is the type II error rate) of 0.8 and significance level (α, type I error rate) of 0.05)

Stratum	Estimated number of invitations in the study arm (n)	Sample size needed in the study arm (n)
Arabic	650	388
English	700	379
Polish	1100	356
Somali*	250	241
Urdu	750	373
Total	3700	388

Since the attendance rates and the possible number to invite differs for each stratum, we also calculated the minimal detectable differences based on expected attendance rates and invitations in the control groups (Table 3). Smaller differences for each stratum will not be considered statistically significant.

Table 3: Expected number of invitations, attendance rate, minimal detectable difference to show statistically significant difference, and estimated lowest attendance rate in the study arm that will be significantly higher than the expected rate in the control arm

Stratum	Expected number of invitations in each arm (n)	Expected attendance rate in control group	Minimal detectable difference	Lowest attendance rate in the study arm that will be significantly higher*
Arabic	650	40%	8%	48%
English	700	54%	8%	62%
Polish	1100	50%	6%	56%
Somali*	250	14%	10%	24%
Urdu	750	34%	7%	41%
Total	3700	40%	3%	43%

*Attendance rate in control group + minimal detectable difference.

7.4 Variables of interest

The randomization variable is the country of birth, and the intervention variable is the invitation letter. In addition, we will extract the following background variables from the Cancer Registry of Norway databases for women born in the actual cohorts invited to screening in the study period: date of birth, residential address, date of immigration, country of birth, date of screening invitation, date of attendance, screening history and screening result, breast cancer.

7.5 Provision for interim analyses

Attendance will be analysed for each stratum to see if it meets the termination criteria at Q1, Q2 and Q3.

7.6 Criteria for terminating the clinical study

This study will be terminated if all strata meet the following criteria at any of the given time points: **A statistically significant *reduction* in attendance rates.** If any of the strata meet the criteria, that strata will be terminated. By "terminated", we mean that we will no longer send invitations in any other languages than Norwegian to the randomized women.

7.7 Specification of subgroups

Each stratum (subgroup) will be analyzed in addition to subgroups based on background variables, meaning we will provide tests for differences and rate ratios for among other the following subgroups:

1. Arabic-speaking women defined as women born in Algeria, Egypt, Iraq, Lebanon, Morocco, Palestine, Sudan, Syria, or Tunisia
2. Polish speaking women defined as women born in Poland.
3. English speaking women defined as women born in the Philippines.
4. Urdu speaking women defined as women born in Pakistan.
5. Somali speaking women defined as women born in Somalia.
6. Age groups: <55, 55-59, 60-65 and 65+
7. Women living in Oslo.
8. Women living in the rest of Norway.

7.8 Treatment of missing, unused, spurious data

We do not expect any data to be truly missing.

8 Data management

After trial participants are identified, a pseudonymized dataset will be extracted, and randomization will be performed. The randomization variable will be coded into the screening database, and the individual trial participant will be automatically invited in the correct language. Data on invitation and attendance will be automatically registered in the screening databases, as per current routines.

The invitation system registers when an invitation is sent, at which point an invitation number (accession number) is created. When the woman shows up for screening, a radiographer registers the woman in the dedicated screening software. Errors in this dataflow are extremely rare, but a quality assurance script will be run once every month to make sure all women with a screening result have data on attendance. There will be no external data review. Tables and other statistics from this quality assurance will be presented to the project leader and principal investigator once every month.

All data system security is handled as per the routines of the Cancer Registry of Norway. Data is stored in an encrypted and secured database for sensitive information, with external backups. A data security team at the Cancer Registry of Norway ensures that all security procedures are followed and that security systems are up to date. Please see the **data management plan** for a more thorough description of the data management in this project.

The data used only for this study is the randomization variable. This information will be retained until 31st of December 2030.

9 Amendments to the research protocol

The Research Protocol may require to be amended during the conduct of a clinical study. Any amendment to the Research Protocol will be agreed upon between the project leader and the principal investigator. The amendments will be approved by the Norwegian Directorate of Health which accepted this study (20/33385-2).

10 Deviations from the research protocol

The study will be performed in accordance with this research protocol. All research protocol deviations will be reviewed by the data manager for impact on subject's participation in the clinical study. The representative for the responsible research institution will notify the project leader and principal investigator of deviations. All deviations will be reported to the appropriate regulatory bodies as required.

11 Statements of compliance

Statement of compliance with ethics principles: The study will be performed in accordance with the ethical requirements defined in the Declaration of Helsinki. Statement regarding ethical approval: The study shall not commence until written approval/favourable opinion from the Norwegian Directorate of Health.

12 Informed consent process

In accordance with the approval from the Norwegian Directorate of Health, this study does not require informed consent. This project is a quality assurance project with an exception from the patient confidentiality that allows for data to be collected and shared between members of the project group for this specific project, granted by The Norwegian Directorate of Health.

13 Suspension or premature termination of the clinical study

Criteria for suspension of the whole clinical study: The study may be terminated by the representative for the research responsible institution or the investigator at any time. However, all women will still receive invitations and screening examinations as normal. The statistical termination criteria to be considered by the DSMB is described in chapter 7.7.

Criteria for un-blinding: All data will be unblinded if, during monitoring of the study, it is discovered that any woman have received the wrong letter of invitation.

Requirements for subject follow-up: Follow-up in this study is defined as the patient going through the normal screening and assessment pathway for breast cancer diagnosis and treatment, if found, and receiving invitations and screening examinations as normal after the end of the study.

14 Publication policy

Upon study completion the results of this study will be submitted for publication in a journal of the project leader's choice and posted in a publicly assessable database of clinical study results. The results of this study will also be submitted to the Ethics Committee according to national regulations. All personnel who have contributed significantly with the planning and performance of the study (Vancouver convention 1988) may be included in the list of authors.

15 Bibliography

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Appendix – invitation letter and leaflet

Invitasjonbrev

Faktaark