

Evaluation of a mobile mammography unit. Concepts and randomized cluster trial protocol of a population health intervention research to reduce breast cancer screening inequalities

Elodie Guillaume (✉ elodie.guillaume@unicaen.fr)

Caen University: Universite de Caen Normandie <https://orcid.org/0000-0002-9169-8197>

Quentin Rollet

Caen University: Universite de Caen Normandie

Ludivine Launay

Centre Francois Baclesse Centre de Lutte Contre le Cancer

Séverine Beuriot

Université de Caen Normandie: Universite de Caen Normandie

Olivier Dejardin

CHU Caen: Centre Hospitalier Universitaire de Caen

Annick Notari

DIS Orne

Elodie Crevel

Centre régional de Coordination des Dépistages des Cancers - Normandie

Ahmed Benhammouda

Centre Régional de Coordination des Dépistages des Cancers - Normandie

Laurent Verzeau

Centre Régional de Coordination des Dépistages des Cancers - Normandie

Marie-Christine Quartier

Centre Régional de Coordination des Dépistages des Cancers - Normandie

Guy Launoy

UNICAEN: Universite de Caen Normandie

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Abstract

Background

Breast cancer is the first women cancer in incidence and mortality in France. Organized breast cancer screening (OBCS) has been implemented nationwide since 2004, but the participation rate remains low (48%) and inequities in participation were reported. Strategies as mobile mammography units could be effective to increase participation in OBCS and reduce inequities, especially in underserved areas in regard to this screening. Our main objective is to evaluate this device and to identify how to incorporate a mobile unit in the OBCS with a view to tackle territorial inequities in OBCS participation.

Methods

A collaborative project will be conducted as a randomized controlled cluster trial in 2022–2024, in remote areas of 4 French departments. Small geographic areas have been constructed by clustering women eligible to OBCS, according to distance to the nearest radiology centre, until an expected size of eligible women was reached, determined according to logistic constraints and respect of the economic model. Intervention areas were then selected by randomization in parallel group. The main intervention is to propose an appointment at the mobile unit in complement to the current OBCS in these remote areas according to the proportionate universalism principle. Few weeks before this intervention, local actors will carry out actions to promote OBCS with mobile unit specific information tools, applying multilevel, intersectoral and community empowerment principle of action to tackle inequalities.

Discussion

This randomized controlled trial will provide a high level of evidence in assessing the mobile unit effects on participation and inequities. Contextual elements interacting with intervention will be a key challenge in this evaluation and the quantitative approach will be completed by qualitative approaches within the RCT to provide elements of knowledge on the causal mechanisms that may modulate the effectiveness of the intervention and to define key elements of its transferability at a national level with the definition of new screening policy for tackle inequities.

Trial registration

Registered on ClinicalTrials.gov, December 21, 2021 : NCT05164874,
<https://clinicaltrials.gov/ct2/show/NCT05164874>

Background

Cancer remains the leading cause of death and a pathology where health inequalities are particularly marked. These inequalities stand at all stages of the medical history of the disease, and are revealed with indicators as incidence, survival and mortality. Regarding detectable cancers as breast cancer, screening appears as a key step in the construction of inequalities.(1) In most European union member states, breast cancer screening is organised with a mammography screening. However, there are still differences in the way screening programmes are implemented.(2) In France, breast cancer is the first women cancer in incidence and mortality with 58968 new cases estimated for 2017 and 11883 death for the same year. (3) Public health policy has organized screening in the general population for this cancer, according to European recommendations and implying a high quality assurance. The organized breast cancer screening (OBCS) has been conducted, nationwide since 2004. A screening mammography is offered every two years to women aged 50 to 74 at average risk for this cancer. They receive from management structures in charge of this screening (SMS), an invitation to visit an accredited radiologist's office. A radiological imaging of the breast with two views plus a clinical breast examination is realized. Two different radiologists assure readings. In the last three year, the national participation rate remains stable around 48% [Santé Publique France], which is lower than the European recommendation set at 70% in view of the expected mortality reduction target.(4) However, it persists a so-called individual screening, apart from age and time recommendations, and that would be achieved by about 15% of women.

A large literature report studies on determinants of non-adhesion to the OBCS, in a great number of countries with different organization and screening modalities and concerning diverse populations (low income, ethnic group, rural areas).(5, 6) Consensually established determinants are usually grouped in five categories. (a) Socio-demographics characteristics as age, marital status, low income; (b) environmental characteristic as living in rural areas (7); (c) health system utilization: having a general practitioner; (d) health behaviour as doing other screening, alcohol or tobacco consumption; (e) psychological factors as beliefs and concern. Most of these factors are socially determined, and considerable social inequalities in participation in OBCS are reported. In France, participation rates vary considerably across geographical areas, with some departments having a participation rate close to the European benchmark while others have a very low rate (< 25%). At a finer level (infra-communal) there are also large differences in participation. In particular studies, using ecological indices of deprivation (8), highlight social and territorial inequalities: women living in disadvantaged area or far from a radiologist's office less participate.(9– 12)

The World Health Organization (WHO) define the social determinants as the main causes of inequalities in health. These are the circumstances in which people are born, grow, live, work and age, and the systems set up to deal with the disease. These determinants are multiple, stand to individual from global policy and act in complex interactions. Determinants of non-adhesion to the OBCS can also be considered according to the social ecological model which incorporate all social and ecological factors that can affect breast screening participation.(13) In summary, individual factors refer to demographic, socio-economic determinants and health behaviours. Interpersonal factors concern social support and network. Community factors refer to cultural norms and community organization. Health system factors concern health insurance, distance to health facility and finally structural factors are relative to wealth

inequalities and place of residence. These determinants when modifiable can be the target of intervention to increase OBCS participation and reduce inequalities in participation.

Different strategies can be implemented to increase participation to breast cancer screening, especially in populations with low-income or in rural areas, who have less access to screening. Among these strategies, mobile mammography units are currently operating in many countries: USA (14), Brazil (15), and at least 7 in European Union (16). MMUs can be included in the national program of organized cancer screening (Sweden (17), or in regional program (10, 14, 18), in addition to a national screening program. The literature underlines that MMU can increase access for under-screened groups by increasing physical and economic access to screening while reducing barriers for women (structural barriers and out-of-pocket costs). However, very few studies allow a high evidence-based evaluation by randomised controlled trial. Moreover, regardless of their target, while the social and territorial inequalities in participation in screening are proven, the majority of evaluated interventions have not taken the existence of these inequalities into account in their design and have not set out to reduce social and territorial inequalities in participation as an objective with the risk to increase it.(19) Nevertheless, it is now well established, when implementing public health interventions aimed at reducing socio-territorial inequalities, that we have to consider some consensual recognized principles: the existence of a social gradient across the whole society, the relevance and the value of the principle of proportionate universalism (20), the multilevel, intersectoral, multidisciplinary nature of the intervention.(21)

In France, a MMU is used for 30 years in a rural area of 279755 inhabitants in 2019, without any prospective trial protocol. Its retrospective evaluation suggests that, when used in remote areas, it could reduce social and territorial inequalities, in particular inequalities due to the distance to an approved radiology centre.(10) However, the potential value of this MMU depends on many local characteristics such as socio-demographic, geographical and medical characteristics. Therefore, in the French context, there is very little evidence on how to intervene to reduce health socio-territorial inequalities in screening, so public health decision-makers are unable to base proposals on evidence. Only an experiment rigorously conducted and evaluated over a large territory and considering contextual determinants would make it possible to establish the true effectiveness of the MMU according to the environment in which it is used and to establish the optimal conditions of its efficiency throughout France.

We present here a randomised controlled trial of a population health intervention research conducted as a collaborative project to reducing or even eliminating territorial inequalities in participation to the OBCS in France remote areas. With a complementary objective to identify the most efficient modalities to incorporating a mobile mammography unit in the organization of breast cancer screening.

Methods

A multi-partenarial project

This project, since the first step, is elaborated as a collaborative, multi-partenarial and intersectoral project. It involves several research teams, the screening management structure (SMS) (Centre Régional de Coordination des Dépistages des Cancers Normandie), institutional partners, local (departments) stakeholders and associations. The project is managed by U1086 INSERM research team (ANTICIPE), who is in charge of design and evaluation. The SMS is in charge of organizing the OBCS (collecting data, consent, sending invitations, organization of second reading and managing follow-up). The 4 French departments where the intervention will take place in Eure, Calvados, Manche, and Seine-Maritime, have invested for the purchase of the MMU. This reflects a strong political will to act against health inequalities and medical desertification in these rural departments. During the two years of the intervention the MMU is made available free of charge to the SMS. This structure is in charge of MMU maintenance and recruitment of the necessary staff (driver, secretary, radiology manipulator and doctors). Doctors of the four departments concerned by the intervention are partners in the study and they have accepted to make working day in the MMU. The MMU itinerary is established in collaboration with a research team in geography IDEES UMR CNRS 6266. Their objective is to optimize the MMU journey by integrating various logistic constraints as distance, parking space available. Other research collaborations are established with a social worker institute (Institut Regional du Travail Social - IRTS) for listing all medical, social and associative resources that could be mobilized for screening prevention (networks of social workers, health centres and medico-social services, associations). These local actors, are responsible to inform women about the OBCS and the MMU. For this task, the institute in charge of the promotion of health on the territory (Promotion Santé Normandie - PSN) is also involved, especially for the actors' coordination, to ensure a common knowledge base on OBCS and to develop new communication tools dedicated to OBCS at MMU. The reflexion on the intervention implementation, interaction between local actors and women, the MMU and women led to an intervention theory development. The project evaluation is based on this theory, developed in collaboration with the AAPRISS platform (Apprendre et Agir Pour Réduire les Inégalités Sociales de Santé). This interdisciplinary platform is specialized in social determinants of health and social inequalities in health.

A steering committee was formed at the start of the project with one or two representatives of the main partners. Scientific decisions are made in partnership with the screening structure. The frequency of meetings has gradually increased to one per week. The SMS database complies with the regulations in force on the protection of health data. Procedures for the circulation, recording and extraction of data relating to project monitoring have been drafted in order to guarantee the quality and confidentiality of the data.

Institutionally, for research part, the project is funded by the French National Cancer Institute (Institut National du Cancer) for 48 months, by the regional health agency (Agence régionale de Santé Normandie) in charge of the OBCS application and with a prize awarded by the association "Ruban Rose" (<https://www.cancerdusein.org/>).

Intervention

The main intervention consists in a proposition for an appointment at the MMU in complement to the current OBCS. This complementary mode of screening offers the possibility for women furthest away from the radiologist's office to undergo screening in the MMU. All women eligible for OBCS and living in the zone selected for the intervention are invited by the screening management structure, to participate either in a radiologist's office or in the MMU, keeping the choice of their place of screening. For women in the control group, the breast cancer screening organisation is not modified. The MMU is equipped with a latest-generation digital scenographer as well as an ultrasound system according to the compliance rules of the specifications published by the National Institute of Cancer. The quality of the mammographic radiographic equipment is also certified by the Nuclear Safety Agency. Compliance with the specifications is ensured by the presence on board of the MMU of a radiology operator and a doctor. The first reading will be made immediately if the doctor is a radiologist and if necessary an enlargement, additional images or an ultrasound will be performed. This procedure currently represents between 15% and 20% of all mammographies performed. Else the first reading is differed and organised with a radiologist by the SMS. In both cases, for normal first reading, the second reading of the mammography will be insured by another radiologist through screening management structure, identically to the current organisation of the OBCS.

About two weeks before the MMU is parked, local actors, carry out actions to inform women on the organized breast cancer screening and on the MMU. Women receive the timetable of these actions with the invitation to participate in screening. Actors inform women about the MMU which is for the majority of women an unknown device. To support these prevention actions, a MMU-specific information tools are developed according to the literacy principle to inform women and to improve women's knowledge of this screening and its organization. In addition, a dedicated site <https://mammobile-normandie.fr/> allows to inform women on OBSC and MMU. A video explains the steps of breast screening in MMU. Timetables of MMU and prevention actions are available and information tools are downloadable. The actors know the protocol and its challenges, and the importance of respecting the intervention and control groups. Prevention actions are organized in concert with the research team and are sized to mainly reach women in the intervention group. However, in the intervention zone, information actions stay under the actor's responsibility and may differ according to the actor's availabilities, prevention profile and expertise, the characteristics of the population, the territory, the logistical constraints, the means and the support that actors are able to mobilise.

Design

This intervention is conducted during two years from March 2022 as a prospective randomized controlled cluster trial in the general population in the departments of Eure, Calvados, Manche, and Seine-Maritime (Normandy Region in the north west of France, except the Orne department, which already has a MMU). The schedule of enrolment, intervention, and assessment is shown in Table 1. This protocol is reported according to the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Table 1

This territory of the intervention represents a surface of 23791 km² and just over 3 million inhabitants. The cluster of the study is a group of IRIS (Ilots Regroupés pour l'Information Statistique), IRIS being the smallest scale for which census data are available and representing an average of 2000 inhabitants. Thanks to the geomatics' tools of the MapinMed platform of the U1086 INSERM (National platform officially labelled by the National League against Cancer), all the women constituting the target population for breast cancer screening in Normandy is geolocated and geocoded (CNIL authorization N ° 921203). Thus, for each woman, history of screening, the current date of screening invitation, IRIS of residence, level of social deprivation according to the European Deprivation Index (EDI) and the distance between the woman's house and the nearest approved radiologist's centre are extracted from the SMS database or calculated (EDI, distance). EDI is an ecological deprivation index constructed according to the Townsend concept of relative deprivation(8, 22). It is calculated as the sum of weighted census variables. The 2011 French version of EDI is computed for each IRIS as $0.32 * \% \text{ Country birth} + 0.36 * \% \text{ Citizenship} + 0.21 * \% \text{ Tenure status} + 0.32 * \% \text{ Household size} + 2.42 * \% \text{ No bath, no shower} + 0.36 * \% \text{ Marital status} + 0.87 * \% \text{ Education} + 0.55 * \% \text{ Professional activity} + 0.80 * \% \text{ Months unemployed} + 0.70 * \% \text{ Occupation}$.

The U1086 INSERM research team has developed an algorithm in python v3.0 to constitute clusters integrating some constraints in a regional scenario (for the four departments). Eligible population data were available in the SMS screening database. First it was estimated that the number of intervention days should not exceed 400 over two years (considering holidays, climatic and logistical hazards). Eight hundred days were considered to constitute a control arm. Based from the experience of the Department of Orne (10), it was estimated that 80 to 120 women had to be invited each day, expecting a 40% participation to the MMU, in order to achieve 32 to 48 mammograms daily. From a population point of view, these women needed to be as distant as possible to the accredited radiology centres. We also planned that when possible, the MMU will park at least two consecutive days on the same site so that women will have flexibility in attending. After calculating the average travel time of women to the nearest radiology centre in each IRIS, the selection of the 96,200 women was made (algorithm stopped at the IRIS exceeding maximum population = 800 days of work*120 women = 96,000) in the 1,131 most distant IRIS. To maximize aggregation of IRIS according to the travel time to the radiology centres, the most distant IRIS has been selected and then merged neighbouring IRIS, still by distance run, until reaching areas of the expected population size. This algorithm was applied to all IRIS according to distance rank, until no more aggregation was possible. 91,982 women (95.6%) and 1,067 IRIS (94.3%) were selected in the final population in 356 clusters (with 258 created by the algorithm). This algorithm allows to construct the geographical clusters. Number of women is estimated with previous screening campaign, the real number will be known when the screening invitation will be send. Table 2 represents the cluster repartition between departments and arms. As it is a regional calculation according to a distance criterion, clusters are not equally distributed among department.

Table 2
Clusters and women repartition in each department

Department	Arm	Women Number	N (%)	Cluster number	N (%)
Calvados	Control	14730	26875	54	102
	Intervention	12145	(29,27%)	48	(27,64%)
Eure	Control	14036	27801	58	111
	Intervention	13765	(30,27%)	53	(30,08%)
Manche	Control	8022	15630	30	62
	Intervention	7608	(17,02%)	32	(16,80%)
Seine Maritime	Control	9919	21676	43	94
	Intervention	11757	(23,60%)	51	(25,47%)
Total		91982		369* (356)	
* 13 clusters cover two departments					

Table 2

After this step, a randomization in parallel group have been perform to constitute the intervention arm (n = 178 clusters) and the control arm (n = 178 clusters), corresponding to 45275 targeted women in intervention arm vs 46707 in control arm. Randomization was accomplished using a computer-generated random number. The information on the clusters and the intervention and control group was then recorded in the database of the management structure. Patients, data manger and medical staff cannot be blinded regarding the intervention. The main characteristics of each arm are presented in Table 3. The mean distance in travel time is 20.42 minutes in the intervention arm and 20.48 in the control arm. For the deprivation index more the score is high, more the cluster is deprived.

Table 3
Characteristics of intervention and control arm

	Intervention	Control
Clusters (N)	178	178
Iris (N)	562	505
Women (N)	45275	46707
Travel time (min) Mean [Min-Max]	20.42 [16.2;31.2]	20.48 [16.1; 30.1]
EDI Mean [Min-Max]	-0,77 [-6,5 ;7.4]	-0.87 [-5.6 ;5.8]

Table 3

Figure 1 represent the map of the four departments concerned by the intervention. Black contours represent the boundaries of the departments and grey contours represent those of the IRIS. The intervention areas are coloured pink and the controls grey. The dots represent the radiology office. The calculation integrates the distance to the radiology office of the neighbouring departments.

Protocol modifications will be discussed with partners and funders and If necessary submitted to ethics committees. The trial registration will be updated.

Eligible population

Women invited to the MMU are all women whose last mammogram is more than 22 months old. Compared to the usual cycle of screening campaigns, these are the women invited at the time of the passage of the mobile unit as well as all the women who have not participated since their last invitations. However, if a woman who meets the screening eligibility criteria comes to the mammobile without an appointment, we will not refuse her.

Statistical Analysis Plans

The overall objectives of the study are to evaluate the intervention's ability a) to reduce the socio-territorial inequalities of participation in breast cancer screening in a regional area (Normandy) in setting remote from radiologist's office b) to increase participation rate and c) understand how intervention interact with contextual factors and which causal mechanisms leading to these results in order to identify the optimal modalities for extending the MMU at the national level. Analysis of the intervention will take place at the end of the two years. An interim analysis will be performed for the first department (Eure).

Concerning the first two objectives, the main evaluation criterion will be participation in screening. Information on clusters, invitations and participation of women are available in the SMS screening database and recorded according to the quality criteria necessary for the monitoring and evaluation of the screening. Participation will be measured and compared between the "intervention" and "control" arm, at the aggregate level (cluster) and individual level in intent to treat. In both arm, a woman will be considered a non-participant 18 months after her last invitation. At the aggregate level, the comparison of screening participation will allow us to measure the raw and age-standardized increase in participation due to the intervention. At the individual level, multilevel logistic regressions, considering cluster data, allow to assess the increase in the probability of participating in screening after adjustment of the social deprivation, age and other available individual characteristics. The analysis of all the screening data in the study departments, and in particular the comparison of remote zone ("intervention or" control ") and nearby zone, will allow us to assess the impact of the intervention on reducing geographic inequalities in the Normandy region. Although the calculation of the number of subjects in the study came from a pragmatic approach, the intraclass correlation factor was estimated at 0.0083, which with an average area size of 318.6 women gives a design effect equal to 3.63. So, the minimum significant difference in

participation that we can prove will be 1.5%. Screening quality criteria will also be monitored using all the data available in the SMS database. A particular vigilant will be accorded to the number of lost to follow-up and delays in reading.

In population health intervention research, the effects of the intervention are modified by the characteristics and dynamics of the context in which it is deployed and integrating interactions between the intervention and its context will be a methodological challenge (23). Some factors as the actor's information action even if not controlled, will be prospectively registered in a dedicated database and will be include in the model. More the participation of women in these actions will be questioned when they come to the MMU.

Other factors will stay unknown and will contribute to a residual contextual variance which may remain significant even after adjustment for individual variables. To furthermore explore contextual effect and to provide elements of knowledge on the causal mechanisms contributing to the effectiveness of the intervention the quantitative analyses will be completed by a qualitative approach inspired by the combined approaches that have emerged in realistic randomised controlled trials, using a theory that goes beyond logic models to describe contextual mechanisms and contingencies. (24) An intervention theory is currently developed and related to this theory an auto-questionnaire will specifically explore the components of the Com B model (Capacity, Opportunity, Motivation) mobilized by women thanks to the interventions (MMU, prevention action, MMU-specific information tools) (25–27). A second auto-questionnaire will specifically evaluated the informed choice with the MMU-specific information tools and a third, the satisfaction of women performing their screening at MMU. As three questionnaires will be sent, so as not to solicit the same woman several times, we will randomly select 3 groups of women from the intervention and control arm. Apart from the questionnaire on satisfaction which will only be sent to participating women a few weeks after their participation, the other two questionnaires will be sent to both participants and non-participants.

A medico-economic evaluation will also be performed. A cost-effectiveness analysis of invitation to the MMU (or to a radiologist office) versus invitation to radiologist office (RO) only (usual screening) will thus be conducted from the payer perspective over a time horizon of 2 years, i.e. the duration of a screening campaign. It will determine the efficiency of the invitation to the MMU compared to RO only. The economic evaluation will provide an ICER (Incremental Cost-Effectiveness Ratio) which will represent the incremental cost per additional screen of the invitation to MMU compared with the usual screening procedure. A similar approach was already applied for the retrospective analysis of the Orne department MMU.(28)

Results will be published in research publications and conference contributions. Feedback will also be provided to all partners. Scientific reports will be written for funders.

Discussion

This population health intervention research involves a diversity of actors with the challenge of coordinating their actions according to the conditions and the environment in which they are implemented. The protocol must provide evidence on MMU effectiveness with also the objective of reducing inequalities of participation in organized breast cancer screening. At each stage i.e the protocol, the implementation and the evaluation, the project must integrate the existence and the reduction of these inequalities.(29)

Reducing inequalities

The co-construction of this project by teams of researchers, institutional and local stakeholders from different disciplines in and out the health field is a real strength. It allows us to integrate in the most comprehensive and multidisciplinary way all the issues in the project. This facilitates the implementation of the study and anticipates appropriation of the device by the actors after the two years of the research intervention. As developed before, our intervention scheme mainly in the screening promotion phase plans to include various professionals from the field of health, from the medico-social, social and associative field in the areas concerned. This inter-sectorality between health and social field is essential regarding to the project objective. Although prevention is at the heart of the problem, social and psychosocial aspects are also essential. Taking care of women and integrating care in the process allows women to be more receptive to prevention messages.

Nevertheless, this step is a challenge to reconcile the objectives of each partners and their temporalities. It is time consuming and it has been three years since the idea of this project was initiated. Some aspects of the project are the responsibility of the partners and the research team carrying the project does not have control over the entire project. For example, the MMU is bought by the 4 departments involved in the project, suggesting coordination and sharing responsibilities for all the administrative steps and tasks require by the common purchase. The screening structures remains a central partner for this project, because of their key role in the organization of screening they are, even in rural areas, well identified by women. They also carry out prevention actions in area with weak participation and they already have constituted a network of partners with other actors. This network will be a support for the management of the mammmobile by the screening structure at the end of the two years of the intervention. The device will have to continue on its way without the constraints linked to the protocol. Integrating other disciplines as geography, social psychology into the project is the most difficult and time-consuming aspect due to semantic and tools usage difference and different research objective.

Our project is based on consensual models of the social determinants of health, which take individual behaviours and characteristics (proximal determinants) into account and the living environment (distal determinants or causes of causes) in a causal model of inequalities in health.(30) In the typology of interventions to reduce the social inequalities stemming from the dynamic model of the WHO, this is a multilevel intervention acting at access to service, community and individual level. The MMU corresponds to proposals of complementary modalities in the organization of screening, aiming at modifying the access to screening. The integration of a MMU into the current breast screening campaign will be

performed according to the principle of proportionate universalism, by reserving this additional modality for women living far from a radiologist's office. The actions of the actors with the target population will allow the strengthening of the community empowerment. For example, with car share action to go to the MMU. More, information and specific tools developed according to the literacy principle will improve individual women knowledge on OBCS.

Design

The randomized cluster trial provides the highest level of evidence regarding the effectiveness of MMU. A territorial approach is developed, the intervention targets women who are far from radiology centres approved for screening and this criterion defines the clusters randomized in parallel groups. Other design as stepped wedge or cross-over have been studied, but they are not applicable with a MMU that has to move from zone to zone by optimizing its movements and with logistical constraints. Nevertheless, with this parallel group randomization, there is a risk of contamination. The main criterion being the distance to the radiology centre, the zone to be randomized are neighbour. Even if only women residing in the intervention zone receive an appointment to the MMU, the collective information may cross the boundary between zones. This contamination bias will be monitored and information's action will be adapted during the study if it will prove to be too important.

Another limitation of the study is due to the fact that in our study the MMU is dedicated to the populations most distant from the radiology offices. Thus, even if the results of our study are positive, they will validate the interest of the MMU in reducing territorial inequalities but not necessarily social inequalities. For deprived women the obstacle to screening participation is more at a social or cultural level rather than physical access to the radiologist office. Conversely, remote populations are globally less deprived than urban population but individually heterogeneity in social situation may occur in these rural areas. Our design allowed to address the MMU effect in remote areas and another study will be conducted to address its effect in urban area.

Mixt evaluation

Even if this protocol assesses the potential of using the MMU for reducing territorial inequalities, it also incorporates contextual elements into its construction to identify the conditions in which the MMU can be transferred elsewhere in France and the determinants of its maximal efficiency.

The contextual elements that will be considered will concern firstly the information actions carried out before the passage of the MMU. The effect of these interventions will depend on the actors, their motivations or the means to disseminate information. This will surely lead to heterogeneous results. Others contextual elements will emerge from the intervention theory. In particular, by explaining the mechanisms implemented and on which we must bring knowledge. The theory established for the intervention will allow it to be conceived as a set of dynamic action systems that interact with their context. Our aim is to evaluate how the mobilization of the network of stakeholders can diversify and adapt the sources of knowledge, create new roles, adapting them to a set of constraints. This list is not yet exhaustive, it could include demography, geography, political issues, etc. and so reveal efficient and

effective modalities for transfer the MMU. Some results of this approach could also be useful for the MMU across European countries.

Conclusions

Providing conclusive data and new knowledge about mechanisms for participation in OBCS remains a major public health issue. This article presents the design of a clustered randomized trial to evaluate a mobile mammography unit on breast cancer screening participation and reduction of territorial inequalities in remote zone of a regional area in France. These objectives imply to considering the principles of action to reduce health inequalities. More, as it's a complex population health intervention research, we have to be aware of contextual elements. These elements by interacting with the intervention could modulate its efficacy. Integrating these elements from the design to the analyses of the intervention, should allow us to understand the mechanisms leading to the results and the optimal modalities of transfer of the MMU to other French or European regions.

Trial status

The published protocol corresponds to the protocol according to which the intervention starts. The clusters were defined in October 2019. The first invitations were sent on 02/18/2022 and the first intervention will take place on 03/02/2022. The intervention must take place in 4 departments, for two years. With all the hazards of interventional research, we expect an end of intervention for March 2024.

List Of Abbreviations

AAPRISS

Apprendre et Agir Pour Réduire les Inégalités Sociales de Santé

BC

Breast Cancer

CNIL

Commission nationale de l'informatique et des libertés

EDI

European Deprivation Index

ICER

Incremental Cost-Effectiveness Ratio

IDEES

Identité et Différenciation de l'Espace, de l'Environnement et des Sociétés

INSERM

Institut national de la santé et de la recherche médicale

IRIS

Ilots Regroupés pour l'Information Statistique

IRTS

Institut Regional du Travail Social
MMU
Mobile Mammography Unit
OBCS
Organized Breast Cancer Screening
PSN
Promotion Santé Normandie
RCT
Randomized Cluster Trial
RO
Radiologist Office
SMS
Screening Managing Structure
WHO
World Health Organization

Declarations

Ethics approval and consent to participate

The study has obtained a positive agreement from the ethics committee CEREEES (1477006 Ter)) and from the French data protection authority (n°921203)

Consent for publication

Not applicable

Availability of data and materials

The datasets analyzed during the current study are not publicly available before the end of the analyses of the intervention

Competing interests

The authors declare that they have no competing interests.

Funding

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U1086 ANTICIPE is a League Against Cancer Labelled Team

No funders were involved in the design of the study nor in collection, analysis, and interpretation of data or in writing the manuscript.

Authors' contributions

EG wrote the manuscript. EG, MCQ and GL lead the project. QR developed the algorithm for zone definition. LL computed the deprivation index and map constructions. EG, LG, QR, LL, OD, MCQ and AN participated in the reflection on the design of the study. SB, EC, AB and LV are involved in the implementation of the study. All authors read and approved the final manuscript.

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Table 1

Table 1 is available in the Supplementary Files section.

Figures

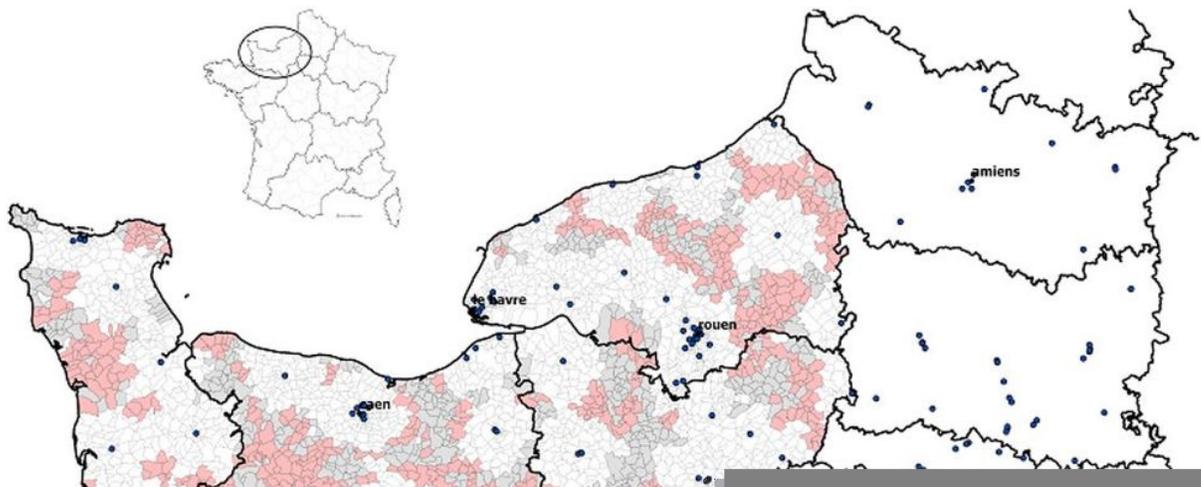


Figure 1

Trial geographic map

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