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Keywords: Mass Screening, Breast Cancer, Cervical Cancer, Primary Health Care, Implementation Science

Posted Date: October 20th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-8950342/v1>

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Additional Declarations: No competing interests reported.

Study protocol for a hybrid type III effectiveness-implementation evaluation of the Detecta-APS strategy for organized breast and cervical cancer screening in Brazilian primary health care

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Abstract

Background: Organized breast and cervical cancer screening is a key strategy to expand access to early detection, reduce inequalities, and decrease mortality. In Brazil, however, the prevailing model remains opportunistic, with weaknesses in the systematic identification and monitoring of the target population, as well as limitations in follow-up. To address these challenges, coordinated actions will be implemented to support the transition from opportunistic to organized cancer screening in the North and Northeast regions of the country. These actions comprise DETECTA-APS, a multifaceted implementation strategy designed to support primary health care teams and evidence-informed decision-making for cancer screening. The present protocol was developed to: (1) analyze barriers and facilitators to the implementation of organized breast and cervical cancer screening; (2) evaluate the effectiveness and implementation outcomes of the DETECTA-APS strategy, and its effects on cancer screening practices; and (3) inform iterative, context-sensitive adaptations of the DETECTA-APS strategy to address implementation determinants and improve

outcomes. **Methods:** This study protocol a hybrid type III effectiveness-implementation evaluation uses a multi-methods design involving patients, health professionals, managers, and the implementation team. Qualitative methods will be used to identify implementation determinants, guided by the Consolidated Framework for Implementation Research (CFIR). Effectiveness and implementation will be assessed using a combination of quantitative (pre-post evaluation) and qualitative methods, guided by the RE-AIM framework, CFIR, with adaptations mapped using FRAME-IS. Participatory methods will then be employed to inform necessary adjustments to the DETECTA-APS strategy. **Discussion:** Reporting this study protocol is important for ensuring transparency, methodological rigor, and reproducibility in the evaluation of complex implementation strategies in primary health care within the public health system. The protocol outlines a structured and context-sensitive approach to examining barriers and facilitators to the organization of breast and cervical cancer screening, assessing the implementation process of the DETECTA-APS strategy, and informing context-sensitive adjustments to improve access, follow-up, and care organization. The findings will provide evidence to inform decision-making by health managers and policymakers regarding the implementation of organized screening strategies, considering regional specificities prior to scale-up.

Keywords: Mass Screening, Breast Cancer, Cervical Cancer, Primary Health Care, Implementation Science

Background

Breast and cervical cancers remain major public health problems, associated with high levels of preventable morbidity and mortality among women, particularly in contexts marked by social and regional disparities [1,2]. In Brazil, despite the availability of screening tests within the public health system, significant inequities persist in access, coverage, and follow-up of care, disproportionately affecting the North and Northeast regions and women in situations of greater social vulnerability [3-5].

Organized and population-based screening approaches for these cancers are recommended through mammography and cytological testing, with the recent incorporation of molecular HPV testing as a promising strategy for cervical cancer screening [6]. However, Brazilian population coverage remains below recommended levels [7,8], reflecting structural, organizational, and social constraints [9,10].

The predominance of an opportunistic screening model in Brazil limits the systematic identification of the target population due to the absence of nominal registries of eligible individuals, failures in active invitation strategies, and inconsistent monitoring and follow-up of performed tests and abnormal results. These structural weaknesses hinder the continuous evaluation of screening outcomes and reinforce existing health inequalities [9,10]. In this context, transitioning to an organized screening model is a priority, particularly in territories historically affected by inequities.

The project ‘Support for the implementation of guidelines for early detection of cervical and breast cancer in primary health care, known as Detecta-APS, is the result of a partnership with the Ministry of Health, through the Secretariat of Primary Health Care (SAPS), through the Programme to Support the Institutional Development of the Unified Health System (PROADI-

SUS) [11] , a programme of the Brazilian Ministry of Health that strengthens the Unified Health System (SUS) through partnerships with philanthropic hospitals of recognized excellence, enabling resources from tax exemptions to be invested in projects focused on research, innovation, training, management and improvement of health care.

As implementation is better understood as a dynamic, multi-stage process rather than a single event, process evaluation plays a central role in examining the mechanisms that facilitate or hinder implementation and the integration of changes into routine practice [12]. Despite its relevance, few studies on breast and cervical cancer screening in primary health care report process evaluations in a systematic and transparent manner, and to the best of the authors' knowledge, none have been conducted in Brazil [12-15].

Given the complexity of the implementation strategy (more details can be found in the methods section), a process-oriented evaluation is required to analyze barriers and facilitators to the implementation of organized breast and cervical cancer screening, to evaluate the effectiveness and implementation outcomes of the Detecta-APS strategy, its effects in the screening, and to inform context-sensitive adaptations. This approach allows the identification of implementation determinants and supports targeted refinements of the strategy aimed at improving implementation performance and outcomes in primary health care settings [16].

Accordingly, this article presents a study protocol to evaluate the implementation process of a multifaceted strategy aimed at strengthening organized screening, with the following objectives: (1) identify and analyze the determinants of implementation, including barriers and facilitators that influence the implementation of organized breast and cervical cancer screening, from the perspectives of users, health professionals, managers, and members of the implementation team; (2) evaluate the effectiveness and implementation outcomes of the Detecta-APS strategy, and its effects on cancer screening practices; and (3) report iterative and context-sensitive

adaptations of Detecta-APS and co-create strategies based on implementation determinants and improve outcomes.

2. Methods/Design

2.1 Description of the Detecta-APS operational model and implementation phases

Detecta-APS was designed as a multifaceted implementation strategy to implement the organized model of breast and cervical cancer screening (the intervention in question) in primary health care, particularly in areas historically affected by inequalities, such as the ten health regions selected in the North and Northeast of Brazil by the Ministry of Health (MS) of Brazil, where Detecta-APS will be implemented. The operational design not only organizes the flow of activities but also defines the institutional actors involved at the state, regional, and municipal levels, promoting shared and collaborative management.

The implementation of Detecta-APS will take place in sequential phases over nine months: (1) adhesion phase, during which the GCE and GCM establish institutional commitment and governance structures; (2) state and regional planning workshops to align stakeholders, define roles, and understand the local context; (3) Implementation Cycle 1, comprising the training workshop for the operationalization of stages 1 to 4; (4) Implementation Cycle 2, with the workshop for training and operationalization of stages 5 to 7; and (5) regional and state evaluation workshops to review progress, consolidate learning, and assess implementation advances as shown in Figure 1.

Figure 1: Operational design of the DETECTA-APS strategy throughout implementation for the transition from opportunistic to organized screening.



Source: Detecta-APS Project.

Detecta-aps is composed of strategic actors at different levels of the health systems that enable the construction of objective, shared, and results-oriented management. This structure involves three main bodies: the State Steering Group (GCE), responsible for planning, monitoring, and strategic coordination at the state level; the Regional Implementation Group (GIR), in charge of operational coordination and territorial articulation in the municipalities of the health regions; and the Service Implementation Leader (LIS), a primary care professional responsible for conducting local implementation, leading improvement cycles, organizing workshops, and acting as a focal point between the service and municipal management.

2.1.1 Seven-step implementation cycles Detecta-APS

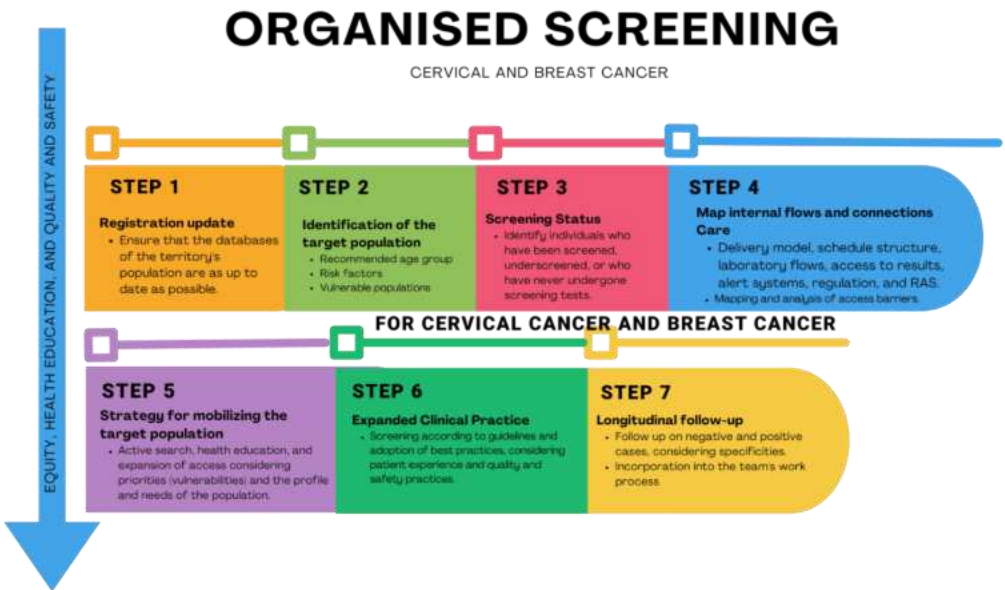
The strategy focuses on supporting organized screening for cervical and breast cancer in primary health care, developed in seven sequential stages (described in Figure 2), and divided into two cycles.

Cycle 1 comprises the operationalisation of the first four stages (1-4): updating population registers, identifying the target population, classifying screening status, and mapping internal

flows and referral networks. Each state and municipality has technical references to support the strategy, and primary care units have a Service Implementation Leader (SIL) who is trained as a local change agent and replicates the training in their units, leading the development and execution of action plans through Plan–Do –Study–Act (PDSA) cycles, a continuous quality improvement methodology that includes iterative planning, implementation, evaluation, and refinement of routine practice.

Cycle 2 follows the same structure of agents and PDSA cycles, but for steps 5, 6, and 7, which refer to population mobilization, expansion of access, strengthening of clinical practice, quality and safety for screening, and longitudinal follow-up.

Figure 2: Stages of the Detecta-APS strategy for the transition from opportunistic to organized screening.



Source: DETECTA-APS Project.

2.2 Participatory development of the study design

The study design was developed using a participatory method called the World Café workshop. This workshop involved representatives from the Ministry of Health (Secretariat for Primary Health Care and Chronic Disease Coordination), the DETECTA-APS operational implementation team, and the researchers responsible for the study.

The World Café methodology was applied for its dialogical and collaborative structure, with collective reflection, prioritisation of problems, and co-creation of research questions in complex health system contexts [17]. This process aimed to align the conceptual foundations of organised triage and implementation science, identify the main implementation challenges in vulnerable locations, prioritise research questions, map the key actors involved, and define priority outcomes and indicators. This ensured that the study design responds to political priorities, operational needs, and contextual realities within the Brazilian Unified Health System.

2.3 Overview of study design

This study adopts a type III hybrid design of implementation and effectiveness, based on the principles of Implementation Science [18]. These are recommended when an intervention already has consolidated evidence, and the main uncertainty lies in how to implement and maintain it in real contexts [19].

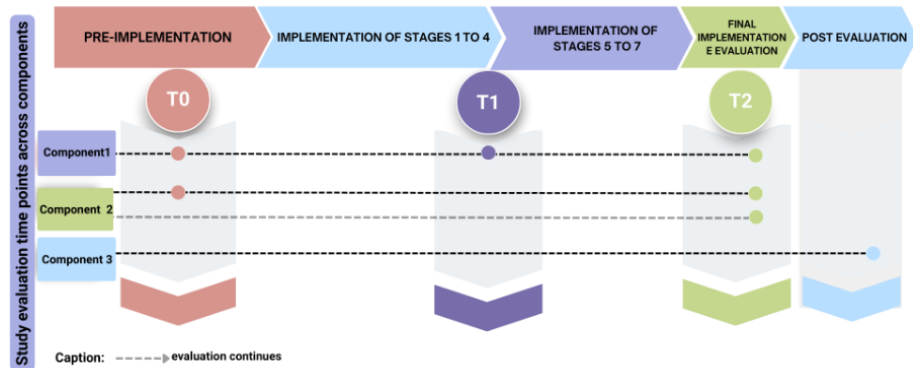
Organized screening for cervical and breast cancer is guided by established national and international guidelines. The primary objective of this study is to evaluate the implementation processes of the DETECTA-APS strategy as a means to support the transition from an opportunistic to an organized screening model. This includes assessing determinants, adaptations,

and implementation outcomes [18]. Additionally, the study will examine service-level effectiveness outcomes using a one-group pre-test-post-test design [20,21].

Accordingly, this study utilizes a multi-method approach that integrates qualitative, participatory, and quantitative methodologies. The research is structured into three interrelated components: (1) Component, investigates the determinants of implementation through a longitudinal qualitative assessment; (2) Component, evaluates the implementation of the Detecta-APS strategy and, secondarily, assesses effectiveness outcomes; and (3) Component, focuses on refining the strategy through co-design workshops held after implementation.

Each component will undergo evaluation at predefined points: baseline (T0), after the first implementation cycle (T1), and after completion of all implementation steps (T2). Component 3 will be evaluated only after the evaluations are completed (Figure 3). This study protocol is reported in accordance with the Standards for Reporting Implementation Studies (StaRI) guidelines [22].

Figure 3: Data collection time points across study components.



Source: Developed by the authors.

2.4 Study context and site selection

The research will be conducted in four states in the Northeast and North regions of Brazil. These states were selected based on the formalization of an agreement between Hospital Israelita Albert Einstein and the respective State Health Departments. In each state, two municipalities were selected: one larger municipality that will receive formative interventions and another smaller municipality.

In addition, we developed a composite indicator incorporating the Brazilian social vulnerability index, as well as variables related to territories characterized by vulnerable populations (high proportions of black and brown residents, quilombola communities, and residents of informal settlements), low screening test ratios, and high mortality rates from cervical and breast cancer. We then created a high–low classification based on the median and applied it to all municipalities [23,24]. The aim was to ensure that we incorporated different contexts of social vulnerability into the study design.

2.5 Participants, sampling, and recruitment

2.5.1 Study population and sampling strategy

A purposive sampling strategy will be used to include key informants aged 18 years or older who are involved in the implementation of the Detecta-APS strategy and/or in organized breast and cervical cancer screening within primary health care.

2.5.2 Participant groups

Participants will be drawn from four main groups: (1) health managers at municipal, regional, and state levels, including members of steering groups and technical areas; (2) members of the implementation teams; (3) primary health care professionals, including service managers and frontline staff; and (4) patients eligible for breast and/or cervical cancer screening.

2.5.3 Eligibility criteria

Eligible patients will include individuals with a uterus and/or breasts residing in the selected regions, within the target age groups recommended for screening (25–64 years for cervical cancer screening and 50–69 years for breast cancer screening), and with the capacity to provide informed consent. Health professionals and managers will be eligible if they are involved in screening activities and/or in the implementation of the Detecta-APS strategy.

2.5.4 Recruitment procedures

Recruitment will occur at different stages of the study and across its three components (T0, T1, and T2). Health managers and members of the implementation teams may participate at all times. Primary health care professionals will be recruited following agreement with local service management during implementation workshops and will be invited directly to participate.

Upon acceptance and provision of informed consent (in person or virtually, depending on the activity format), managers, professionals, and implementation staff will complete a sociodemographic and occupational questionnaire via REDCap and participate in semi-structured

interviews and/or focus groups. Given the possibility of staff turnover, additional recruitment may occur throughout the study, following the same procedures and instruments. Patients will be recruited exclusively in person, in settings that ensure privacy, comfort, and safety, preferably within the health services they attend. After providing written informed consent, patients may participate at T0, T1, and/or T2, completing a sociodemographic questionnaire and taking part in an individual interview related to Component 1 and/or Component 3. Different participants may be recruited for different study components.

2.5.5 Sample size and saturation

The final qualitative sample size will be determined based on interpretive sufficiency (thematic saturation). Approximately 240 invitations across participant categories (managers, professionals, implementation of team members, and patients) are planned. Data collection will be concluded once recurring patterns and sufficient analytical depth are achieved to address the study objectives.

2.6 Study design of components and evaluation structure

2.6.1 Component 1: Qualitative assessment of implementation determinants

This component uses a qualitative, exploratory design to identify and analyze the determinants of implementation, including barriers and facilitators that influence the implementation of organized breast and cervical cancer screening, from the perspectives of users, health professionals, managers, and members of the implementation team. Data will be collected

three times: baseline (T0), after the first implementation cycle (T1), and at the end of implementation (T2) [25].

This component will be guided by the *Consolidated Framework for Implementation Research* (CFIR). This framework, widely used in implementation research, aims to identify the determinants of intervention, that is, the barriers and facilitators that influence the implementation. The CFIR is organized into five domains: Innovation, External Environment, Internal Environment, Individuals, and Implementation Process, and encompasses 48 constructs derived from multiple theories developed to explain the success or failure of interventions [26].

Data collection methods

Data will be collected using focus groups and in-depth interviews, selected according to participant profile and feasibility.

Focus groups: will be preferentially conducted with primary health care professionals, as this method facilitates peer interaction and the exploration of shared practices and collective meanings related to organized screening. Groups will include approximately 6–10 participants, with an estimated 3 to 6 focus groups, depending on territorial diversity and data saturation. Participants who are unable or unwilling to participate in group settings will be offered individual interviews.

In-depth interviews: Health managers, implementation team members, and service users will participate in in-depth interviews, a format considered more appropriate for capturing individual perspectives, including potentially sensitive issues and hierarchical or organizational dynamics.

Data collection procedures

Interviews and focus groups may be conducted in person or remotely, depending on participants' preferences and logistical feasibility. All participants will complete a brief self-reported sociodemographic questionnaire prior to data collection. The following variables will be collected: age, sex assigned at birth, gender, race/ethnicity, educational level, marital status, household income, religious practice, and occupation. The semi-structured interview guides will explore factors influencing the implementation of organized cervical and breast cancer screening, as well as barriers and facilitators related to stages 1 to 4 of the DETECTA-APS strategy at T0-T1 and to stages 5 to 7 at T2.

Focus groups and interviews will be conducted by trained qualitative researchers, with a co-facilitator responsible for observational notes. Sessions will take place in health facilities or workplaces indicated by participants.

2.6.2 Component 2: Evaluation of implementation processes and effectiveness outcomes

This component integrates the evaluation of both the implementation and effectiveness of the DETECTA-APS strategy. Effectiveness will be assessed using a One-Group Pretest-Posttest Design, comparing outcomes at baseline (T0), during implementation (T1), and at the end of implementation (T2). Implementation evaluation will include analysis of the implementation strategy and outcomes, and the systematic documentation of adaptations throughout implementation, using quantitative and qualitative data collected between T0 and T2 [20,27].

Implementation will be evaluated through the analysis of implementation outcomes and adaptations occurring throughout the process, integrating quantitative and qualitative data. This study adopts a complementary multimethod approach, in which quantitative data are used to assess outcomes, while qualitative data are employed to examine implementation processes and outcomes [21]. This integrated approach addresses aim 2 and aligns with recommendations for evaluating complex interventions and strategies, which emphasize the analytical distinction between them, as outlined in the Standards of Reporting Implementation Studies (StaRI) [22] .

Quantitative evaluation

The evaluation will focus on outcomes aligned with the RE-AIM framework [28]. The RE-AIM framework was selected because it allows for the integrated evaluation of both the implementation of the Detecta-APS strategy and its effects on cancer screening practices. By examining reach, effectiveness, adoption, implementation, and maintenance, RE-AIM supports the distinction between implementation performance and intervention outcomes, which is essential when evaluating complex strategies in primary health care settings. This approach enables a comprehensive assessment of how and for whom the strategy works.

Data collection and sources

Quantitative data will be collected at two time points: baseline (T0), immediately before or at the start of the Detecta-APS implementation, and end of implementation (T2). Secondary data will be obtained from national health information systems, including the Cancer Information System (SISCAN) and the Primary Health Care Information System (e-SUS APS), covering the period from January 2022 to December 2026. Additional aggregated data such as number of

women who reside in the assigned area of the Primary Health Care Unit will be obtained from local information systems. Administrative monitoring data produced by the operational team will also complement the analysis. Nominal and individually identifiable data will not be accessed or analyzed.

Qualitative evaluation

Will be performed to complement the quantitative evaluation of outcomes, also following the RE-AIM. A qualitative process will be conducted to examine the adaptations of the Detecta-APS strategy.

Data collection

Data will be collected through focus groups and in-depth interviews. Focus groups will be primarily conducted with primary health care professionals to explore shared experiences and collective practices related to implementation. In-depth interviews will be conducted with managers and members of the implementation teams, and with professionals when individual interviews are more appropriate or when participation in group settings is not feasible.

Guiding questions will focus on understanding how the strategy was operationalized, how implementation processes unfolded, what decisions were made, how fidelity was maintained during implementation, and which adaptations were required throughout the process.

Documentary data

In addition to primary qualitative data, documentary sources produced during implementation (e.g., technical and operational reports, action plans, meeting minutes, monitoring spreadsheets, and other administrative records) will be reviewed to complement and triangulate findings from interviews and focus groups. All documents will be accessed in aggregated and anonymized form.

2.6.3 Component 3: Co-design refinement of the implementation strategy

This component corresponds to the refinement of the strategy, conducted through co-design workshops at the end of implementation. The aim is to understand the key implementation determinants identified throughout the study and the outcomes that did not demonstrate satisfactory results. Based on this, context-sensitive adaptations to the DETECTA-APS strategy will be developed to increase acceptance, engagement, and long-term sustainability, and to strengthen the strategy before subsequent implementation cycles or expansion into new territories.

Co-design is a participatory approach widely used in implementation science, as it integrates stakeholders' experience with system-level knowledge to support shared problem-solving and collective decision-making [29]. In this study, adaptations are analyzed at two analytically distinct moments: during implementation, in Component 2, when adaptations are documented as they naturally emerge; and after implementation, in Component 3, where adaptations are co-designed through participatory co-design.

Participants and setting

Co-design workshops will be conducted at the regional level with groups of 10–15 participants, including primary health care professionals, health managers, patients, and members of the implementation team. Participants may include individuals previously involved in Components 1 and 2, as well as new local stakeholders identified for this phase. Participants were purposively selected to ensure diversity of roles, experiences, and territorial contexts relevant to the implementation of organized cancer screening.

Procedures and data collection

Workshops will be facilitated by trained researchers. Facilitators were trained in participatory methods and reflexive practices to minimize power asymmetries and ensure balanced participation across stakeholder groups. Participants will actively prioritize and decide on proposed adaptations through collective deliberation. The co-design process will be structured into five sequential phases:

Phase 1 – Reassessment of barriers and facilitators (CFIR-guided brainstorming)

Participants will work in small groups organized according to CFIR domains (inner setting, outer setting, intervention characteristics, characteristics of individuals, and implementation process). Using visual brainstorming techniques, groups will reassess previously identified barriers and facilitators, examining their persistence, transformation, or resolution during implementation. Persistent barriers identified in Phase 1 will be linked to potential implementation strategies using the ERIC taxonomy, supporting the systematic naming.

Phase 2 – Prioritization of strategies (GUT matrix)

Participants will prioritize strategies using the GUT matrix (severity, urgency, and trend), assigning scores to each criterion to support consensus-based decision-making under conditions of limited resources.

Phase 3 – Collective validation and synthesis

Prioritized strategies will be presented in a plenary session for cross-group validation and refinement. This process will result in a territory-specific summary document consolidating the prioritized adaptations to inform subsequent implementation waves.

2.7 Data Analysis

2.7.1 Qualitative Data Analysis

This qualitative analysis section refers to all three components of the study. It will follow the specific analytical structures for each component, as described in the Method. Although data analysis, management, and coding are common, the analytical focus will vary according to the objectives of each component and the corresponding theoretical references that guide the interpretation.

Focus group discussions and individual interviews will be transcribed verbatim. In addition, two independent researchers will conduct a full reading of the audio transcripts, revisit written records, and organize the material with the support of ATLAS.ti® software.

The analytical technique employed will be thematic analysis, following Braun and Clarke (2006), using a hybrid qualitative approach that integrates inductive and deductive strategies guided by the domains of CFIR, as well as RE-AIM and FRAME-IS [30,31]. This approach will enable the identification of barriers, facilitators, adaptations, and sustainability-related factors

associated with the implementation of the Detecta-APS strategy across different regional contexts.

The analysis process will follow these steps: (A) thorough reading of transcripts to ensure data familiarization; (B) identification of meaningful excerpts linked to constructs from the selected frameworks; (C) independent coding by two researchers, with discrepancies resolved by consensus or consultation with a third researcher; (D) grouping of coded units into thematic categories; and (E) interpretation of findings in light of the study objectives. To ensure credibility, triangulation of data sources and methods will be conducted, incorporating different participant groups, workshop records, and individual interviews.

Throughout the process, records of methodological decisions, reflexive field notes, and analytical memos will be maintained [30]. As outputs, two synthesis documents are expected: one focusing on barriers and facilitators of the Detecta-APS implementation based on CFIR, and another addressing strategy adaptations and sustainability grounded in RE-AIM and FRAME-IS, as well as inductively emerging findings.

In addition to these analyses, Component 3 will involve examination of written and visual materials (post-its, posters, conceptual maps, and drawings produced during workshops) to support data familiarization and initiate the coding process. During the first round of coding, strategies proposed by participants will be mapped, along with the meanings attributed to them in relation to the barriers and facilitators discussed. Strategies will be grouped by similarity, and a consolidated list will be developed by workshop and by territory, avoiding duplication.

Selected workshop participants will be invited to collaboratively review the final data analyzed. Strategies will be discussed using diagrams, illustrative quotations, and graphical representations produced during the workshops, fostering an iterative process of refinement, review, and validation of attributed meanings. The focus will be on coherence between

participants' statements, produced materials, and the categorization of strategies. In addition, the final data will be triangulated with the synthesis document produced during the workshop.

The trustworthiness of the entire analysis will be ensured through multiple strategies: independent coding by the principal researcher, peer cross-review, active listening to recordings to verify meanings, triangulation across verbal data, graphical materials, and field notes, as well as analytical meetings conducted with members of the local technical team.

2.7.2 Quantitative Data Analysis

Data will be analyzed using statistical software IBM SPSS Statistics version 31.0. Descriptive analyses will be conducted, followed by comparisons between pre- and post-implementation periods (T0–T2). Where appropriate, analyses will be stratified by sociodemographic and contextual variables, including age group, educational attainment, race/ethnicity, and area of residence. Appropriate analytical methods will be used to examine the association between the intervention and its outcomes, adjusting for relevant confounders.

3. Discussion

The transition from opportunistic to organized cervical and breast cancer screening presents significant challenges. In settings marked by structural constraints, regional inequalities, and fragmented care pathways, the effectiveness of screening depends not only on the availability of diagnostic tests but on the system's capacity to identify the eligible population, ensure active invitation, coordinate care, and guarantee timely follow-up of abnormal results [9,10,32].

International experience demonstrates that this transition requires the restructuring of service delivery, stronger coordination of primary health care, and the development of system-level strategies capable of sustaining the organization of care [33]. In this context, studies that evaluate the implementation processes of system-level strategies are essential to validate key operational components, such as governance, quality assurance, information systems, and monitoring, aligned with international best practices for organized screening programs.

In this way, this study contributes by proposing the evaluation of a complex system-level strategy aimed at transitioning from opportunistic to organized screening within the context of primary health care in a public and universal health system — the Brazilian Unified Health System (SUS). By integrating determinants, strategies, and implementation outcomes, the study seeks to understand mediators and mechanisms through which organized screening can be operationalized under real-world conditions in a public health system.

One of the main strengths of the study lies in its methodological approach. The evaluation of a novel and innovative strategy, developed in collaboration with MoH, will be conducted through the integration of qualitative and quantitative methods, combined with longitudinal data collection at different stages of implementation, allowing the analysis of how factors dynamically influence implementation and its outcomes. The multi-level and multi-actor design constitutes another relevant strength. The inclusion of patients, primary health care professionals, managers, and implementation teams makes it possible to understand different dimensions of screening organization and service delivery. The use of data from national information systems, complemented by qualitative data and operational documentation, supports the analysis of implementation under routine conditions and enhances the external validity of the findings. The study also incorporates a territorial and equity-oriented perspective by prioritizing regions historically marked by social and health access inequalities. The consideration of contextual

variables, such as social vulnerability, race/skin color, and geographic disparities, will enable an understanding of how implementation processes and outcomes vary across different contexts and populations. The use of established implementation of science frameworks strengthens the analytical rigor of the study.

Some limitations should be acknowledged. The pre–post design without a control group limits causal inference regarding the effects of the strategy. In addition, reliance on secondary data may be affected by variations in the quality and completeness of information systems across municipalities. The complexity of the strategy and the diversity of participating contexts may also make it difficult to attribute observed effects to specific components, and the implementation period may not be sufficient to fully capture the sustainability of organizational changes.

Despite these limitations, the study has relevant implications for policy and practice in primary health care. The production of evidence on population identification strategies, active invitation, care coordination, follow-up of abnormal results, and equity-oriented approaches may support the organization of screening within the SUS. The findings may also inform context-sensitive planning of practices and policies and contribute to strengthening primary health care as the coordinator of care in cancer screening programs.

4. Results

It is expected that this study will identify structural, organizational, cultural, and socioeconomic barriers to the operationalization of organized screening, as well as recognize facilitators of this process in the North and Northeast regions of Brazil. This phase will support the development of context-adapted implementation strategies, validated by all stakeholders and selected based on their feasibility and implementation capacity.

Regarding study implementation, the DETECTA-APS strategy is expected to promote the adoption of organized screening in primary health care units, strengthen governance and coordination structures, and sustain the involvement of health professionals and managers throughout the implementation cycle. The implementation process is expected to support adherence to organized screening routines and promote the intention to continue the strategy beyond the study period, replacing the opportunistic model.

Secondarily, measurable improvements in screening performance indicators are expected. These include increased mammography coverage (for women aged 50 to 69) and cytopathological and/or HPV testing (for women aged 25 to 64), with a greater proportion of women screened within the recommended range and target age group. Improvements in the proportion of tests, the proportion of tests performed in the target population, and the proportion of initial tests are also expected.

A positive impact on operational indicators is also expected, including increased access to screening among under-screened or never-screened individuals, a greater proportion of tests performed after a formal invitation, a reduction in the average time between abnormal screening results and diagnostic confirmation, and higher return rates to health services.

List of abbreviations

APS: Atenção Primária à Saúde

ATLAS.ti®: Qualitative Data Analysis Software

CAAE: Certificado de Apresentação para Apreciação Ética

CEPPAR: Center for Studies, Research and Practice in Primary Health Care

560 **CFIR:** Consolidated Framework for Implementation Research
561 **DETECTA-APS:** Support for the implementation of guidelines for early detection of cervical
562 and breast cancer in primary health care
563 **e-SUS APS:** Primary Health Care Information System
564 **ERIC:** Expert Recommendations for Implementing Change
565 **FRAME-IS:** Framework for Reporting Adaptations and Modifications to Evidence-based
566 Implementation Strategies
567 **GCE:** State Steering Group
568 **GIR:** Regional Implementation Group
569 **GUT:** Gravity, Urgency and Trend Matrix
570 **HIAE:** Hospital Israelita Albert Einstein
571 **HPV:** Human Papillomavirus
572 **LIS:** Service Implementation Leader
573 **MoH:** Ministry of Health
574 **PDSA:** Plan–Do–Study–Act
575 **PROADI-SUS:** Program to Support the Institutional Development of the Unified Health System
576 **RE-AIM:** Reach, Effectiveness, Adoption, Implementation, Maintenance
577 **REDCap:** Research Electronic Data Capture
578 **SAPS:** Secretariat of Primary Health Care
579 **SISCAN:** Cancer Information System
580 **StaRI:** Standards for Reporting Implementation Studies
581 **SUS:** Unified Health System
582 **T0:** Baseline
583 **T1:** After Implementation Cycle 1
584 **T2:** After Implementation Cycle 2

585 586 **Declarations**

587 588 **1. Ethics approval and consent to participate**

589

The study was approved by the Ethics Committee of the Albert Einstein Israelite Hospital (HIAE/CAAE: 90650425.6.0000.0071). Secondary quantitative data will be in the public or administrative domain, already available for consultation without participant identification; therefore, there will be no requirement for Informed Consent. Regarding the obtaining of other primary data, participation will be conditional upon completion and signing of the Informed Consent Form.

2. Consent for publication

Not applicable, as this is a study protocol; no personal data will be presented in this article.

3. Availability of data and materials

Not applicable, as this is a study protocol; no study results will be presented in this article.

4. Competing interests

The authors have declared that no competing interests exist.

5. Funding

This work was supported by the Program of Support for the Institutional Development of the Unified Health System (Law No. 12,101 of November 27, 2009), through Proadi-SUS – Technical Opinion N° 8/2024 - CGCOC/DEPPROS/SAPS/MS (0043707106) and dispatch CGPROJ/DGAPS/SAPS/MS (0043811687). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

6. Authors' contributions

618 **TSR** conceived and designed the study, led the qualitative and participatory methodological
619 development, will coordinate the qualitative analyses, drafted the manuscript, and coordinated the
620 revisions.

621 **ARO** conceived and designed the study, led the quantitative methodological development, will
622 coordinate the quantitative analyses, and critically revised the manuscript, with a primary focus on
623 quantitative methodology.

624 **IEO** contributed to the overall study design, provided study supervision and strategic guidance,
625 and critically revised the manuscript.

626 **LYA** contributed to the overall study design, provided study supervision and strategic guidance,
627 and critically revised the manuscript.

628 **TR** contributed to the design and coordination of the DETECTA-APS implementation strategy
629 and critically revised the manuscript.

630 **MOC** contributed to the design of the DETECTA-APS strategy, participates in territorial
631 implementation and quality monitoring, and revised the manuscript.

632 **VVGF** contributed to the design of the DETECTA-APS strategy, participates in territorial
633 implementation and quality monitoring, and revised the manuscript.

634 **CCB** contributed to the design of the DETECTA-APS strategy, participates in territorial
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636 **ACRDG** contributed to the study design, will coordinate the qualitative analyses, and revised the
637 manuscript.

638 **CFO** contributed to the study design, will coordinate the qualitative analyses, and revised the
639 manuscript.

640 **DB** contributed to the overall study design, provided study supervision and strategic guidance, and
641 critically revised the manuscript.

642 **RGS** contributed to aligning the study with the Ministry of Health's priorities and revised the
643 manuscript.

644 **NSS** contributed to aligning the study with the Ministry of Health's priorities and revised the
645 manuscript.

DCPS contributed to the overall study design, strengthened the Implementation Science framework, drafted sections of the Introduction and Discussion, and critically revised the manuscript.

7. Acknowledgements

Not applicable

8. Authors' information (optional)

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