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*A nurse-led medical tattooing clinic for breast cancer patients:
development and feasibility of a complex intervention in health
services research*

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To those who fight.

To those who are learning to live after battle.

To all the rocks learning to become rivers,

choosing to see colors on dark.

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Foreword

It was an honour to carry out this important project, which will help to complete the treatment pathway for patients who have fought breast cancer. The scholarship came at just the right time. I felt that I wanted to do more and that I could express myself through research. This has been the case from the beginning. Of course, I could never have imagined all the ways in which I would change. Every event and person I encountered was part of this transformative journey. I give each of them the greatest credit for conveying their joy in what they do despite the difficulties of everyday life.

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Finally, thank you to my biggest fan and the greatest and most talented teacher of all: you, who will be proud of me even when I discuss this thesis, wherever you are.

Thank you, Dad.

Synthesis

Background

The Nipple-Areola Complex (NAC) tattooing is a valuable technique for breast reconstruction after cancer surgery. Compared to surgical procedures, it offers several benefits, including reduced costs, shorter waiting times and fewer complications, as well as high patient satisfaction with aesthetic results. This technique can be used on its own or in combination with other methods, such as skin grafts. It is also the only option for patients with contraindications to surgery, such as damaged tissue or comorbid conditions. In Italy, it is often performed by professional tattoo artists, resulting in significant financial costs for patients. However, since 2019, NAC tattooing has been included free of charge by the National Health Service as part of essential levels of care, which highlights its complementary role in the breast cancer care pathway. Nurse-led NAC tattooing services can be cost-effective and provide patients and their families with a safe, specialized referral. Despite its benefits, the lack of in-clinic NAC tattooing services remains a barrier to equal access to this care. Furthermore, more research is needed to fully understand the impact of this intervention on women's lives, healthcare organizations, and professional competency.

The hypothesis to be tested is that developing and implementing a NAC tattooing service in the local health authority of Reggio Emilia will reduce the burden on women in their care and survivorship journeys. Furthermore, the impact will be multifaceted, influencing not only patients' psychophysical recovery, but also their families, the community, professionals, and the organization. The service will complete the breast cancer care pathway in a sustainable and innovative manner. This project aims to develop and evaluate the ARCADE (AReola CApezzolo DEermopigmentazione) clinic, a nurse-led NAC tattooing service for patients who have undergone breast cancer surgery at Azienda USL-IRCCS in Reggio Emilia. The impact on patients, professionals, and the organization will be assessed.

Methods

This objective will be pursued through a multi-phase health services research methodology incorporating adaptability, continuous evaluation, and community engagement. NAC tattooing within an oncological context is an example of a complex healthcare intervention. Such interventions consist of multiple interacting components and are frequently implemented within service delivery contexts across diverse fields. The intricacy of the intervention depends on various factors, including the number of interactions and behaviors involved, the diversity and expertise of the professionals involved, the instruments used, the outcomes to be assessed, organizational characteristics, logistical considerations

and the degree of flexibility inherent in the intervention. The Medical Research Council's framework for developing and implementing complex healthcare interventions was followed. This included intervention development (WP1): WP1 began with a scoping review (Step A), which aimed to examine the available evidence about NAC tattooing reconstruction after breast cancer surgery. Step B aimed to identify theories, contextual elements, and areas of interest in developing the intervention. Step C involved developing an initial plan of activities by integrating the evidence collected in Step A and the contextual analysis from Step B. The feasibility and evaluation phases (WP2) aimed to assess the feasibility of establishing a nurse-led NAC tattooing clinic. An observational, mixed-methods study was implemented for this purpose. The objectives were firstly to assess the organizational sustainability of the nurse-led NAC tattooing clinic (Endpoint 1), secondly to evaluate the cosmetic outcome of the NAC tattoo (Endpoint 2), thirdly to explore professionals' perceptions of their involvement in the NAC tattooing clinic (Endpoint 3), and fourthly to explore tattooed women lived experiences (Endpoint 4).

Results

Results from WP1 revealed that research on NAC tattooing is pertinent, despite methodological deficiencies, as it helps women to redefine their identity following debilitating cancer treatments. The main findings suggest the need for further research into processes and outcomes. A contextual examination was performed by engaging stakeholders, including patients, support groups, families, and healthcare professionals. Patient and public involvement were crucial. The identification of professionals, healthcare services, materials, and settings was planned. The initial procedure and activity scheduling were set.

Results from Work Package 2 (WP2) showed that a nurse-led NAC tattooing clinic is a feasible complex intervention for breast cancer management. According to Endpoint 1, a retrospective analysis of activity and process data from the ARCADE clinic revealed that the activity exhibited standard characteristics in terms of timing and materials. All the participants in the study ($n = 33$) achieved a satisfactory cosmetic result, with no adverse events or other complications. The second endpoint of the study involved a panel of experts analyzing photographs of the tattooed NAC. These were analyzed according to objective criteria, including symmetry, coloring, and the 3D effect. A total of 22 sets were retrospectively retrieved and demonstrated excellent quality, achieving medium scores of 4.7 and 4.8 out of 5 for color similarity and symmetry, respectively, and 4.7 for the 3D effect. Moreover, five professionals were interviewed to explore the barriers and facilitators encountered. Integrating the analysis of the retrieved data that were generated by the qualitative approach highlighted the pivotal role of resource availability and personnel motivation in achieving goals, as well as promoting

accountability and developing competence. Implementing this service established a support network in which the community and professionals collaborated to provide this final step of care, which can be crucial for psychophysical recovery. The ten patients interviewed for Endpoint 4 contributed significantly to filling research gaps in this area. The findings of the study indicate that participants identified two key strengths of the service: accessibility and reliability. Furthermore, a correlation was evidenced between NAC tattooing and body image perception. This encompasses a spectrum of actions, ranging from the simple act of seeing oneself in a mirror to consistently observing one's identity as a woman. This enabled women to attain a novel perspective on their identity, fostering a sense of normality, confidence and healthy self-perception. A noteworthy finding is the positive role that the participants identified in coping: the past, characterized by illness and prolonged treatment, is perceived as having less impact and intruding less profoundly.

Discussion

This project demonstrated the potential of health service research in combining different outcomes and effects. In addition to confirming its effectiveness, this project illustrated the methodology for creating a customized care model and its correlation with patient outcomes and the values of the professionals involved. The results highlight the importance of implementing ARCADE within the public health service, as it results in positive effects on daily life, intimacy, and social participation. The implementation of ARCADE could facilitate the completion of the breast cancer care pathway, thereby fostering equitable access for patients. Providing services such as ARCADE demonstrates clear value in terms of competence, equity, and the right to health. However, several challenges remain, such as ensuring dedicated and motivated personnel, creating data-driven models for quality assessment, improving team coordination and sharing of information, maintaining and evaluating competence, validating specific training and, most importantly, reconciling long-term sustainability with high-level performance.

Conclusions

NAC tattooing is a highly effective therapeutic intervention. The nurse-led ARCADE clinic has been shown to address a significant gap in patient care and is considered valid, safe and equally accessible. NAC tattooing is a vital part of the psychosocial recovery process for breast cancer survivors, helping to restore body integrity and personal identity. Further studies are required to confirm these findings. However, preliminary findings suggest that improving body image perception may facilitate social functioning and psychological recovery from the impact of disease and medical treatment.

Introduction

Breast Cancer represents a significant and pervasive global health challenge [1]. In 2022, it was the most common cancer diagnosed in women in 157 out of 185 countries, underscoring its worldwide impact [1]. Countries with robust healthcare systems and dedicated programs have successfully achieved annual mortality reductions of 2–4%, primarily through effective early detection, timely diagnosis, and advanced treatment protocols [1]. A multidisciplinary, evidence-based, and integrated approach brings quality to care, which is often long and complex. Treatment for breast cancer includes several options, which are often combined based on the patient's characteristics: surgery, radiotherapy, chemotherapy, hormone therapy, and biological therapy [2]. When surgical treatment is indicated, it can affect quality of life even years later. The approach may be conservative, removing only the portion of the breast affected by the tumor, or it may involve removal of the entire breast, including the nipple. In the latter case, reconstructive surgery may follow to implant a replacement prosthesis after removal [2]. Once the breast reconstruction phase has been completed, it is possible to undergo outpatient surgery for surgical reconstruction of the nipple. The latter allows the breast's appearance to be completed painlessly. This technique involves the creation of two small skin flaps raised and sutured together. After healing, the breast will have a nipple recreated with skin flaps taken in situ, of the same color as the surrounding skin. Reconstructive surgery often provides excellent results in breast shape. However, areola and nipple tattoos are a neglected part of the breast reconstruction process [3]. This can be performed in combination with plastic surgery to achieve an even more realistic result.

1. The impact of surgery: coping and female identity

Women with breast cancer who undergo extensive surgery have worse body image, sexual health, and anxiety than women who undergo less extensive surgery [4]. Breast reconstruction can play an important role in coping among breast cancer patients. However, it is not so easily accepted by many women due to a multitude of factors. Thus, it is essential to have proper intervention programs in place to ensure women can cope with this situation and can lead healthy lives [5]. Notably, the perception of one's body may no longer be in harmony with personal or social expectations. This loss of familiarity with one's body may result in a refusal of the part of the female body that is most charged with symbolism and meaning, both personal and collective: even simply looking in the mirror can be experienced as devastating. These physical changes can significantly compromise a woman's identity and her relationship with her own body, to the point of also significantly affecting her relationships

with others [6, 7]. Any woman who receives a breast cancer diagnosis suddenly experiences extreme psychological distress, not only because of the meaning and implications of the pathology itself, but also because breasts are a part of the body that symbolically and concretely represents femininity. Therefore, if a diagnosis and the subsequent chemotherapy and/or radiotherapy leave a deep mark on a woman's life, surgery, despite increasingly less mutilating procedures, leaves an indelible mark which is visible daily. Moreover, the touch of an incomplete breast causes a psychological wound that affects all areas of life, including the physical, relational, and professional spheres [8].

2. Body image-related health issues

Aesthetic outcomes are emotionally linked to the experience of illness, role identity, hope for the future, and recovery of one's 'self' [9]. Themes of support, emotions, loss, and relationships are involved in body image awareness after mastectomy or breast reconstruction [10]. Psychosocial consequences such as the interruption or loss of a career, changes in one's role in the family, and significant changes in one's social life can be significant. Body image perception is a complex psychological experience that includes evaluations, beliefs, feelings, and behaviors related to physical appearance. Thus, the related suffering is perceived globally and may contribute to several health issues: breast cancer survivors have raised risks of anxiety, depression, fatigue, sleep disorders, pain, and sexual dysfunction, compared with women with no history of cancer [11], and women who undergo mastectomy also suffer from stress and trauma [5]. In particular, the impact of scarring is reflected in physical, social, emotional, and cognitive functioning, thus affecting quality of life [12]. This makes supportive interventions for processing body image increasingly necessary, since their early implementation is likely to benefit long-term health of cancer survivors [5, 11]. A growing body of evidence suggests that the medical tattoo on mastectomised women is an approach with therapeutic value, promising to regain femininity, sexuality, and identity, after the experience of disease and destructive treatments [13, 14]. Considered as the end of a painful process, it completes a course of treatment with the recovery of bodily and psychophysical integrity [13].

3. The Nipple-Areola Complex (NAC) tattooing

The NAC tattooing, or dermopigmentation, is a promising non-surgical technique for reconstruction of the NAC [15]. It represents a conclusive step in breast cancer surgery (with or without surgical reconstruction of the nipple), reconstructing breast appearance. NAC tattooing intervenes downstream of the diagnostic-therapeutic pathway to restore a balance and recover, also psychologically, the patient's well-being and a good final aesthetic outcome.

The intervention consists of coloring the skin through the introduction of specific pigments into the superficial layer of the papillary dermis with the help of an electric device and disposable needles [16]. This technique was first introduced in 1975 [17], and then it has been refined [15, 18]. Medical tattooing has a wide range of applications in various clinical areas [19]. It differs from artistic tattooing or permanent make-up in terms of its purpose, the materials used, and the techniques employed. Firstly, the treatment is intended for individuals requiring reconstruction or coverage of pathological skin conditions following invasive procedures such as chemotherapy, radiation therapy or reconstructive treatments, with the aim of restoring the appearance of healthy skin integrity. Secondly, pigment is inoculated into the NAC using different types of injectors, with needles of various thicknesses and speeds, that can puncture the skin at a consistent depth. In semi-permanent cosmetic tattooing, the color fades over time, so yearly touch-ups are recommended to maintain optimal results. Working in this field requires artistic and technical skills in drawing and pigmentation, as well as an understanding of dermatological, oncological, and surgical elements [20], since the act of tattooing a compromised skin in an individual who likely suffers body image and identity issues requires specific attention. Crucial technical considerations include color harmonization, needle depth and range, dermograph angle, and achieving a three-dimensional effect [21]. The pigments used, which can be organic, non-organic, or a combination of both, are used to achieve the desired shade of color and are deposited more superficially compared to permanent make-up techniques. In Europe, REACH regulations set out requirements for pigments such as sterility and the total exclusion or maximum reduction of metal derivatives [22]. Products must also be labelled with information such as the lot number, quantity, expiry date and a list of components [16]. The synergy of these factors reduces the risk of pain, excessive bleeding, infections, and skin reactions. It also increases the chance of achieving an excellent three-dimensional and natural appearance, as well as ensuring pigment persistence, versatility, and personalized outcomes [16].

4. Rationale

The NAC tattooing has been demonstrated to engender a reduction in costs, waiting times, and associated complications when compared with surgical procedures of reconstruction. The satisfaction levels of the aesthetic results have also been demonstrated to be high [23]. The tattoo can be performed in isolation or in conjunction with other reconstruction techniques, such as skin grafts, to ensure integration of color and appearance [24 - 27]. Furthermore, it is the sole viable option in the event of contraindications to surgery, such as damaged tissues, comorbidities, or anxiety associated with prior hospital experiences [27, 28]. However, the experiences documented in the existing literature differed in terms of management aspects according to healthcare contexts. Although in Italy NAC tattooing

was recently included in the essential levels of assistance guaranteed by the National Health System (NHS), free of charge, [29], this technique is frequently executed by trained tattoo artists, with significant financial implications for patients. Nurse-led multidisciplinary services for NAC tattooing allows for a safe referral and, compared to the surgical reconstruction of the NAC, has been demonstrated to be cost-effective, since it is an outpatient procedure [23, 30 -32]. In-clinic NAC tattooing services are not widely implemented in Italy. Moreover, the impact of this intervention on women's lives, healthcare organizations, and professional competence remains to be elucidated.

5. Hypothesis

The hypothesis to be tested is that the development and implementation of a NAC tattooing service in the local healthcare context of Reggio Emilia will reduce women's burden in their care and survivorship journey. Furthermore, the impact will be manifold, exerting influence not only on patients' psychophysical recovery, but also on their family, the community, the professionals and the organization. The service will be on track to complete the breast cancer care pathway in a sustainable and innovative manner.

6. Aim

This project aims to describe how a nurse-led NAC tattooing service addressed to patients who have undergone breast cancer surgery in the setting of Azienda USL-IRCCS of Reggio Emilia, can be developed and adapted to the local healthcare context, also assessing its feasibility and impact on patients, professionals, and the organization. The objective will be pursued through a multi-phases methodology of health services research described in the following chapter, with these key elements: adaptability, continuous evaluation, and community engagement.

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Chapter I

Methodology

1.1 The context of the Health Services Research

Health Services Research (HSR) is an essential interdisciplinary field of inquiry dedicated to the assessment of healthcare system and service performance [1]. HSR is characterized by its commitment to generating evidence on the structure, process, and outcomes of care, systematically examining crucial domains such as quality, effectiveness, access, efficiency, and equity within complex operational settings [2]. Its scientific mandate is to understand how organizational structures, financing mechanisms and social context influence patient outcomes, thereby bridging the gap between clinical discoveries and their successful application in diverse, dynamic settings [2].

The integration of quantitative and qualitative data, as facilitated by the mixed-methods approach, has been demonstrated to be particularly effective in delivering a comprehensive understanding of complex health phenomena [3]. A critical distinguishing feature of HSR, when compared with clinical research, is its aim to see the system as a whole, analysing the constraining forces exerted by organisational structure, financing systems, policy, and social factors on access and quality [4].

The overarching objective of HSR is not merely to delineate issues, but rather to facilitate the allocation of resources and the development of policies, thereby contributing to the establishment of learning health systems in which research is seamlessly integrated into the delivery of healthcare. This macro-level orientation naturally necessitates the incorporation of policy analysis, resource allocation and finance, thus rendering HSR crucial for government and large organizational decision-making [5].

The Donabedian Model is conventionally utilized by HSR to establish the framework for the evaluation of the quality of care [5]. The framework under discussion categorizes quality assessment measures into three domains:

- Structural measures: These instruments are utilized to evaluate the capacity and organizational characteristics of the provider, including but not limited to staffing ratios, facility certifications, and financial resources.

- **Process Measures:** These metrics encompass various domains, including the delivery and utilization of care, such as waiting times, adherence to evidence-based protocols, and the time required to implement interventions.
- **Outcome Measures:** These assess the results of care, which HSR categorizes into two types: service outcomes and patient outcomes.

The ambition of HSR, therefore, necessitates the development of specialized research areas, such as complex interventions research and implementation science, to supply the rigorously tested solutions and strategies required to effect change within the system. The implementation science field of research examines the methods that facilitate the systematic integration of evidence-based practices into standard clinical procedures. Implementation science employs hybrid designs that simultaneously measure the effectiveness of an intervention, that is its fidelity, acceptability, adoption, and sustainability, and the success of the implementation strategy, focusing on the analysis of organizations, teams, or providers as its primary unit [6]. The methodological pathway that characterizes HSR is indicative of the challenge inherent in evaluating solutions that are neither straightforward drug trials nor unambiguous policy changes, but rather multi-dimensional healthcare programs. The majority of these initiatives are defined as complex interventions [7].

1.2 The Complex interventions' research

Complex intervention research can be approached from an efficacy, effectiveness, theory-based, and/or systems perspective. The selection of a specific perspective is contingent upon extant knowledge and the potential contributions of additional evidence to the corpus of knowledge. Complex intervention research is an interdisciplinary field that goes beyond the conventional question of whether an intervention achieves its intended outcome. Instead, it asks a broader range of questions, including the identification of its other impacts, the assessment of its value relative to the resources required to deliver it, the theorizing of its workings, the consideration of how it interacts with the context in which it is implemented, its contribution to system change, and the use of evidence to inform real-world decision-making [8].

1.2.1 Definition

An intervention may be considered complex due to several inherent properties. The number of components involved, the range of behaviors targeted, the expertise and skills required by those delivering and receiving the intervention; the number of groups, settings, or levels targeted; and the permitted level of flexibility of the intervention or its components [8]. The flexibility in intervention

delivery and adherence can account for variation in how, where, and by whom the interventions are delivered and received. Standardisation can thus concentrate more on the underlying process and functions than on the specific form of components delivered. This necessitates a theoretical deconstruction of the intervention into its components and the establishment of an agreement on the permissible and prohibited variation in their delivery. The implementation of the intervention can vary across different contexts, while ensuring that the fundamental components of the intervention are maintained.

It is evident that complexity frequently arises from interactions between the intervention and its context. The term 'context' is defined as any feature of the circumstances in which an intervention is conceived, developed, implemented, and evaluated [8]. It is imperative to focus attention towards this interaction to comprehend the manner in which interventions affect change, and the circumstances in which they are most effective. This emphasis underscores the necessity to identify mechanisms of change.

It is therefore essential to pay close attention to the design of the intervention itself, as well as to the conditions that are necessary to realize its mechanisms of change. In addition, consideration must be given to the resources that are required to support its reach and impact in real-world implementation. Within this theoretical framework, complex interventions can be productively viewed as events in systems. A systems perspective facilitates comprehension of the dynamic interaction between the intervention and the context [8]. Systems are frequently characterized as complex and adaptive, exhibiting properties such as emergence, feedback, adaptation, and self-organization. For research to be of maximum utility, it is essential that it considers the complexity arising from both the intervention's components and its interaction with the implementation context. The utilization of complex interventions is a prevalent phenomenon within health and social care services, public health practice, and various domains of social and economic policy that bear health implications. Such interventions, which may range from novel surgical procedures to the redesign of healthcare programs or shifts in welfare policy, are delivered and evaluated across multiple levels, encompassing the individual up to the societal scale.

1.2.2 The necessity for a contemporary framework

In 2000, the United Kingdom Medical Research Council (MRC) initially established a guiding framework for researchers and funders concerning the development and evaluation of complex interventions [9], that has been subsequently revised [7]. Despite the continued influence of these foundational documents, which have been supplemented by more specific and detailed guidance on

specific research aspects, significant evolutionary changes have occurred in the theoretical and methodological landscape since 2006.

The development of the novel framework was primarily motivated by the imperative to address the calls for a shift in research priorities, specifically the advocacy for a greater allocation of effort and funding towards research that can achieve the most significant impact on healthcare and population health outcomes [8]. The preceding paradigm, frequently focused on the question of establishing effectiveness, has been the subject of critique for potentially failing to deliver interventions that are implementable, cost-effective, transferable, and scalable in real-world conditions. The objective is to facilitate collaboration between researchers and stakeholders with a view to identifying key research questions concerning complex interventions. The intention is also to design and execute research that employs a diversity of perspectives and methodological choices that are appropriate to the task.

The new framework incorporates recent advancements to maximize the efficiency, utility, and real-world impact of research. The approach is explicitly pluralistic, integrating a variety of methodologies and perspectives. It asserts that enhancing theoretical frameworks and gaining deeper insights into the mechanisms through which interventions influence change, including their interaction with context and broader dynamic systems, are of equal importance to obtaining unbiased estimates of effectiveness [8]. This comprehensive perspective is essential for delivering solutions relevant to real-world practice.

An exemplification from nursing practice can be observed in the context of hourly rounding practices in hospitals, where nurses proactively assess patients' needs, provide fundamental care, and address any concerns or queries they may have. The efficacy of these practices has been substantiated by numerous studies, which have documented positive outcomes such as enhanced patient satisfaction, reduced call light utilization, decreased falls and pressure ulcers, and optimized nursing workflow [10]. However, significant challenges to implementation have been identified. Firstly, nurses may encounter difficulties in prioritizing hourly rounding amidst their other responsibilities. Secondly, staffing shortages and high patient acuity can impede the consistency of rounding on patients every hour. While the efficacy of an intervention in a controlled trial setting is evident, its implementation in real-world settings may be constrained by factors such as staffing, workload, and organizational culture [10].

In synthesis, the updated guidance is indicative of several core conceptual and methodological shifts:

- **Integration of systems thinking and context:** The novel framework underscores the notion that interventions are most efficacious when conceptualized as events within systems. This dynamic perspective on the interaction between an intervention and its context, encompassing

system properties such as emergence, feedback, adaptation, and self-organization, is imperative for generating findings that are most beneficial to decision-makers .

- Expansion of research perspectives: It is argued that there have been many 'effective interventions' led by researchers that have achieved little real-world impact due to a lack of consideration of implementation requirements and stakeholder insight [11]. To facilitate the selection of appropriate research questions, the following four research perspectives are introduced: efficacy, effectiveness, theory-based, and systems. The selection of perspective is contingent upon the research questions that seek to be addressed, and these are determined by identifying the key uncertainties that exist [11]. This ensures that complex intervention research is equipped to address questions beyond internal validity and efficacy, encompassing the real-world challenges of implementation, resource allocation, and system change.
- Prioritizing utility over certainty: The framework posits a trade-off between obtaining precise, unbiased answers to narrow questions and more uncertain answers to broader, more complex questions. Researchers are encouraged to prioritize answering questions deemed most useful to decision-makers over those that can merely be answered with greater certainty.

The framework for developing and evaluating complex interventions divides the research process into four phases and integrates six core elements that must be considered throughout all stages.

1.2.3 The Phases

The framework delineates four phases, which are not necessarily sequential, and researchers may initiate the study at any point depending on the extant uncertainties. In circumstances where uncertainties persist, it is preferable to employ a repetitive approach to phases, as opposed to an automatic progression [8]:

- Develop or identify the intervention: The preliminary phase encompasses the development of a novel intervention or the adaptation of an extant one for a novel context. This is to be grounded in research evidence and theory of the problem. As an alternative approach, the identification of an existing intervention (whether policy-based or practical in nature) is recommended, followed by an exploration of options available. This process is frequently facilitated by conducting an evaluability assessment.
- Feasibility: The feasibility phase is a process which is used to assess the feasibility and acceptability of both the intervention and the evaluation design. The objective is to facilitate

informed decision-making regarding progression to the subsequent stage of evaluation. At this stage of the process, the predefined progression criteria related to the evaluation design (e.g. recruitment, data collection) or the intervention itself (e.g. optimal content, acceptability, likelihood of cost-effectiveness) are to be assessed. It is possible to conduct an evaluability assessment in this context, with a view to ascertaining the viability of conducting an evaluation of the intervention in question, and to determine the most appropriate method of doing so.

- **Evaluation:** The present phase pertains to the assessment of an intervention, with the most suitable method being employed in order to address the research questions. Evaluation is understood to be a broad concept, extending beyond the conventional question of whether an intervention is effective. It encompasses a comprehensive exploration of the intervention's extensive impact, the formulation of theoretical explanations for its functionality, consideration of its interactions with context, and an evaluation of its contribution to systemic transformation. The selection of an optimal research perspective (efficacy, effectiveness, theory-based, or systems) and the prioritization of answerable and useful research questions are fundamental to this approach.
- **Implementation:** The final phase of the process is characterized by deliberate efforts to increase the impact and uptake of health innovations that have been successfully tested. It is imperative to anticipate implementation questions within the program theory and to give due consideration to these throughout all the preceding phases. Key considerations include attention to the components of the implementation strategy and contextual factors that support or hinder its impact, along with implementation-specific outcomes such as reach or uptake.

1.2.4 The core elements

It is imperative to consider and continually revise a common set of six core elements throughout all the four phases above-described, with particular emphasis on the transitions between these phases. These elements support the analysis of fundamental research questions in the domain of complex intervention research [8].

- **The context:** as defined in paragraph 1.2.1, is the way the intervention interacts with its context. The effects of interventions are frequently found to be contingent on context, which is regarded as both dynamic and multi-dimensional.
- **Program theory:** Program theory delineates the anticipated mechanisms through which an intervention is expected to engender its effects, in addition to the conditions under which these

effects are to be realized. It elucidates the fundamental components of the intervention and the way they interact, the mechanisms of the intervention, and the characteristics of the context that are anticipated to influence those mechanisms, as well as the way those mechanisms might influence the context. Program theory can be utilized to foster shared comprehension of the intervention among diverse stakeholders and to identify pivotal uncertainties and research inquiries.

- **Stakeholders:** The term 'stakeholder' is employed to denote individuals who are targeted by the intervention or policy in question, those involved in its development or delivery, or those whose personal or professional interests are affected (that is to say, all those who have a stake in the topic). Patients and the public are recognized as key stakeholders in this process. It is imperative to engage with the relevant stakeholders at each stage of the research process in order to optimize the potential for developing or identifying an intervention that is likely to have a positive impact on health and to enhance the likelihood of achieving changes in policy or practice.
- **Key uncertainties:** The design and execution of research must engage pragmatically with the multiple uncertainties involved, offering a flexible and emergent approach to their exploration. Consequently, researchers are advised to allocate time to developing the program theory and clearly identify the residual uncertainties. They should consider the existing knowledge identifying the research team and the stakeholders' for the most significant elements to be determined. The formulation of research questions is informed by judgments about the key uncertainties, which, in turn, govern the choice of research perspective.
- **Intervention refinement:** Intervention refinement is an integral component of complex intervention research, occurring at each phase of the research process. At the transition from one phase to another, the intervention may necessitate of refinement, based on the data collected or the development of the program theory. The feasibility and acceptability of interventions can be enhanced by engaging potential intervention users to provide insights that inform these refinements.

1.3 The project outline

The methodological phases described in paragraph 1.2.3 were crucial in pursuing the objective of this project: to describe how can a NAC tattooing service be developed and adapted to the local healthcare

context, also assessing its feasibility and the impact on patients, professionals, and the organization. We organized the project into work packages (WPs).

WP1 outlined the initial development phase, and comprised three steps:

- Step A: it aimed to examine the available evidence about NAC tattooing reconstruction after breast cancer surgery. As illustrated in Chapter II, a scoping review was conducted to synthesize grounding literature exploration.
- Step B: it aimed to identify theories, contextual elements and areas of interest in developing the intervention. As illustrated in Chapter III, a contextual examination was performed by engaging with key stakeholders, including patients, associations, families and professionals. Patient and public involvement was crucial for collecting information on the implementation context of a co-designed project, as well as for promoting participation through meetings and events.
- Step C: it aimed to develop an initial plan of activities by integrating the evidence collected in Step A and the context analysis of Step B.

Chapters IV and V will provide information on WP 2, that focuses on the feasibility phase. Specifically, an observational, single-center, mixed-methods study was conducted to evaluate the feasibility of a NAC tattooing nurse-led clinic for women who have undergone surgical treatment for breast cancer in Reggio Emilia local healthcare context. The study aimed to evaluate: organizational sustainability (Endpoint 1); cosmetic results (Endpoint 2); the experience of professionals (Endpoint 3); and the experience of women who undergone treatment (Endpoint 4). The methods were as follows:

Quantitative analysis

- Endpoint 1: A single-arm observational study was conducted using retrospective data to evaluate the first endpoint through the analysis of ARCADE clinic activity and process data collected during the clinic's first 20 months of operation (January 2023 to August 2024).
- Endpoint 2: A panel of experts analyzed and evaluated photographs of the final result of each completed NAC tattooing treatment according to objective criteria (symmetry, coloration, and 3D effect).

Qualitative analysis

- Endpoint 3: A qualitative study of professionals involved in various capacities (technical, scientific, care and organizational) in the clinic's activities. This was conducted through semi-structured interviews.
- Endpoint 4: A qualitative study of women treated at the ARCADE clinic, conducted through semi-structured interviews. The findings related to Endpoint 4 will be presented in Chapter V.

Further studies will address the implementation phase.

In all the chapters mentioned, the core elements described in the previous paragraph will be assessed, with an emphasis on the context and stakeholders, which played a crucial role in the project's overall development and assessment. Notably, there is a growing consensus that the active involvement of patient and public involvement and engagement (PPIE) in care services and research development, from design to evaluation, is fundamental to achieving equitable outcomes for all. The PPIE concept has evolved and expanded over time, with efforts being made to clarify it. PPIE is a collaborative model involving patients, carers, and community members. It emphasizes sustained partnerships, shared contributions, equitable power distribution, and active involvement throughout the research process [12]. PPIE engages with diverse populations and addresses the needs of underrepresented and disadvantaged groups, promoting health equity [13]. PPIE is also an integral aspect of participatory action research and community-based participatory research. The field of oncology is a favorable ground for PPIE applications, since it empowers us to address the rapidly changing needs and priorities of a growing population affected by cancer [13].

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Chapter II

Background on NAC tattooing

Submitted as:

Tattooing to reconstruct Nipple-Areola Complex after oncological breast surgery: a scoping review

By

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Supportive Care in Cancer

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Abstract

Purpose: The dermopigmentation of the Nipple-Areola Complex (NAC) is a safe non-surgical reconstruction technique that can restore psychophysical integrity, representing the final step after oncological surgery. This scoping review aims to identify and synthesize the literature focused on medical tattooing for NAC reconstruction in women who underwent breast reconstruction after cancer

surgery. Competence and training, outcomes and organizational aspects were assessed as specific outcomes.

Methods: The Joanna Briggs Institute (JBI) methodology for scoping reviews was followed. MEDLINE, Embase, Cochrane Library, Clinical Key, Scopus and Cinahl databases were consulted. After title (N = 54) and abstract (N = 39) screening and full-text review (N = 18), articles that met eligibility criteria were analyzed, critically appraised and narratively synthesized.

Results: 13 articles were analyzed, with full texts (N = 11) and only abstract (N = 2). The overall quality of the literature (N observational studies = 11; N pilot experimental studies = 2) is weak. Nurses were the professionals mostly involved (N = 6), then medical staff (N = 4) and tattoo artists (N = 2). The professional training is poorly described in 6 papers. The most frequently assessed outcome was the satisfaction rate (N = 8). One study explored aspects of quality of life with a validated questionnaire. The management of these services resulted variable. Nurse-led services were implemented in 2 studies.

Conclusion: Despite methodological weaknesses, NAC tattooing research is relevant because it helps women redefine their identity after demolitive cancer treatments. Further research on processes and outcomes is needed.

Introduction

At the end of 2020, breast cancer was the most prevalent cancer in the world [1]. If the tumor position is found in the tissues below the areola or on the surrounding skin, Nipple-Areola Complex (NAC) removal may be necessary. This procedure can compromise the aesthetic result of breast reconstruction and have a substantial psychological impact on the patient [2]. The NAC medical tattooing, or dermopigmentation, is a simple and safe non-surgical reconstruction technique that leads to recovery by restoring the psychophysical integrity [2]. It can reduce costs, waiting times, and related complications compared to surgical procedures. High satisfaction levels of the aesthetic results are also demonstrated [3]. The tattoo can be performed alone or with other reconstruction techniques, such as skin grafts, to integrate color and appearance [3-6]. Moreover, it represents the only possible option in case of some contraindications (damaged tissues, comorbidities, anxious states related to past hospital experiences) [7, 8]. Rees initially introduced the technique in 1975 [9], and it has been recently refined [10, 11]: the sterile/semi-sterile skin pigmentation is performed by a specifically trained professional through the introduction of natural pigments into the superficial papillary dermis with a disposable needle, through a dermographer or manually [12]. The experiences reported in the literature differed in professional and management aspects according to healthcare contexts. In Italy, this technique is

usually performed by professional tattoo artists [8], with considerable costs for patients. Nevertheless, some encouraging experiences of in-clinical services are growing as the final part of the breast reconstruction after cancer surgery and treatment clinical pathway [8, 13]. NAC dermopigmentation is included in the essential levels of assistance guaranteed by the National Health Care System, free of charge [2]. The implementation of nurse-led multidisciplinary services can be cost-effective (no operating room is needed) [2], [3].

Further, this service can represent a familiar patient referral through the therapeutic relationship with the clinical nurse specialist [14, 15]. Nurses are essential in supporting women in making informed decisions about all aspects of their care [16]. Until 2010, only a handful of small studies examined patient satisfaction following NAC tattoo reconstruction, as they were relatively the first experiences studied [17]. After a preliminary search of MEDLINE and the Cochrane Database of Systematic Reviews, two narrative reviews investigating tattoo techniques and theories were found, with poor robustness in methodology and quality assessment of evidence [3, 8]. How this intervention impacts women's lives, healthcare organizations, and professional competence is unclear. No systematic or scoping review on the topic was found. This scoping review aims to identify and synthesize the literature focused on medical tattooing for NAC reconstruction in women who underwent breast reconstruction following breast cancer surgery.

Methods

A scoping review methodology was chosen, as it provides a literature mapping on a specific topic, showing relevant concepts, gaps in the research, and types of existing evidence [18]. This review will gain the general objective by answering the following primary research question: what is the evidence about medical tattooing for the NAC reconstruction in breast cancer patients who underwent surgical treatments? Additionally, specific outcomes will be achieved by answering the following secondary research questions:

1. What type of professionals, competence, and training are involved in providing the intervention?
2. Which outcomes and/or Patient Reported Outcomes (PROs) are assessed in the studies?
3. How is this intervention delivered in the healthcare settings considered by the studies?

The proposed scoping review was conducted following the Joanna Briggs Institute (JBI) methodology for scoping reviews [19]: the process started with defining the objective and question, followed by developing the inclusion criteria, evidence research following the planned strategy, selection, and

extraction of the evidence, analysis, presentation, and summarizing the evidence. This scoping review was reported by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist [20].

Search strategy

The PICO method (P = population, I = intervention, C = control, O = outcome) was used to make the research question. The women who underwent breast reconstruction following breast cancer surgery treatment were included in the population frame; the intervention considered was the tattoo performed to reconstruct the NAC; no control was assessed; outcomes are described above. A literature search was conducted within the following databases: Pubmed, Embase, Cochrane Library, Clinical Key, Scopus, and Cinahl. The main keywords “Nipple-Areola Complex” and “tattoo” were used in Pubmed and also adapted in the other databases with the keywords “nurse”, “breast” and “dermopigmentation”. The records were filtered by time frame (from 01/01/2010 to 28/02/2023) and involved subjects (Human). Reference lists of included papers were manually checked to find further records.

Eligibility criteria

Studies that considered the intervention in association with other techniques for NAC reconstruction were included, as well as those evaluating staff perceptions, other organizational outcomes, and any measurable change in health conditions. This review considered complete and primary published literature: all experimental study designs, prospective and retrospective cohort studies, case-control studies, analytical cross-sectional, descriptive observational study designs including case series, and descriptive cross-sectional studies. Qualitative studies were also evaluated. Exclusion criteria were listed as follows: non-English languages; incomplete or unpublished literature, conference papers, case reports, and theoretical/position papers. We excluded papers that described other reconstruction methods alone. Finally, we excluded studies that explored the tattooing technique in other regions different from the NAC, with a non-reconstructive aim (for example, decorative/artistic tattoos), and those involving non-oncological patients.

Study selection

The study selection process is presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review (PRISMA-ScR) flow diagram (Figure 1) according to the PRISMA-ScR statement [20]: the search results were imported into Mendeley software and screened for eligibility by two independent reviewers in each phase. Duplicates, as well as non-relevant records, were manually removed in two steps: firstly, evaluating the title and the abstract, and secondly, after

the full-text reading. Any reviewer disagreements were resolved through discussion at each stage of the selection process.

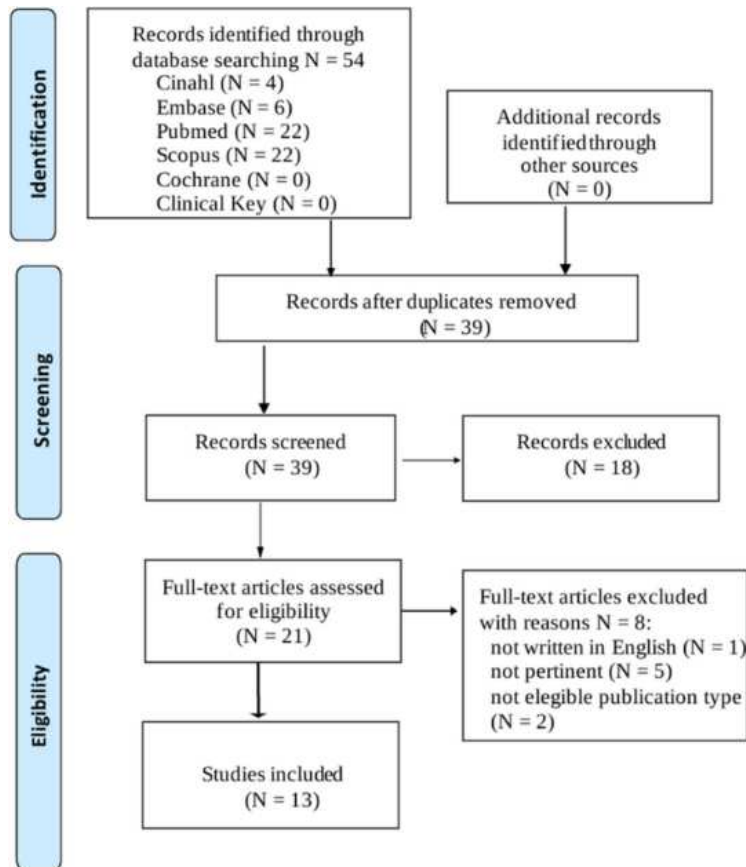


Figure 1 - PRISMA Flow Diagram for the scoping review process.

Data extraction

One reviewer manually extracted the data from the selected articles using Excel, which was cross-checked independently by another review team member. Any disagreement identified was resolved through discussion with other review team members. If full texts were unavailable, the abstracts were considered in the analysis, reported, and discussed separately. Extracted data included author, year, Country, population, methods, adverse events, and main results. These elements were sought according to the specific outcomes stated before. A narrative and thematic synthesis was conducted to summarize the results.

Critical appraisal of included literature

Studies were critically evaluated according to the Equator network's reporting guidelines [21]. Secondly, a more profound quality assessment was conducted with the Effective Public Health Practice Project (EPHPP) [22]: for clinical trials, randomized clinical trials (RCTs), and observational studies, it is a widely used instrument with an excellent degree of inter-rater reliability. The score's sum of the six domains (selection bias, study design, confounders, blinding, data collection methods, withdrawals, and drop-outs) constitutes the overall quality rating, which can be "strong", "moderate" or "weak". Two independent reviewers conducted a quality assessment and discussed and solved any discrepancies. This step provided more certainty when referring to this intervention, specifically on how it should be methodologically evaluated and implemented in different healthcare contexts.

Results

Literature search results

As represented in Figure 1, the literature search identified 54 records: 22 from Medline, 6 from Embase, 0 from the Cochrane Library, 0 from Clinical Key, 22 from Scopus and 4 from Cinahl. After removing 15 duplicates, 39 articles were screened by title and abstract reading. 21 papers were assessed for eligibility: 8 studies were excluded: not written in English (N=1), not pertinent (N = 5) and not eligible publication type (N = 2). Finally, 13 articles were included in the review. Eleven studies included the full texts, while 2 were available as abstracts only.

Characteristics of the included literature

The articles involved participants from Europe (n = 6), America (n = 4), Asia (n = 2) and Oceania (n = 1). Observational studies were the most frequent results (n = 11), while two were pilot experimental studies. Papers were classified by publication type (full texts or abstracts). Eight studies evaluated the satisfaction rate given by the patients, and three the aesthetic results, mostly considering appearance and symmetry [10], color match [23]; one study also evaluated the perceived usefulness of the NAC tattoo service [2]; one paper aimed to identify the risk factors for tattoo-related breast infections [13]; two studies focused on the relationship between radiotherapy and tattoo fading [24, 25]; one study involved healthcare personnel, determining if the likelihood of discussing options for NAC tattooing differed between Registered Nurses (RNs) and non-RNs [26].

Quality Assessment

As reported in Table 1, the overall quality of evidence is weak: most of the results were observational studies (based on medical records [13], with small samples [6], not methodologically rigorous [23, 25, 28]). Another limitation was found in the outcome measurement: none of the studies used validated instruments except one [29]. The experimental studies aimed to evaluate the technique's safety and the intervention's feasibility, with the need for larger and more structured projects [2, 11].

Paper	EPHPP
Gava et al. (2020)	Moderate
Weissler et al. (2021)	Moderate
Uhlmann, Martins and Piato (2019)	Weak
Smallman et al. (2018)	Weak
DiCenso and Ficher-Carlidge (2015)	Weak
Sowa et al. (2021)	Weak
Goh et al. (2011)	Weak
Cha et al. (2019)	Weak
Murphy et al. (2010)	Weak
Starnoni et al. (2020)	Weak
Aslam et al. (2015)	Weak

Table 1 - Quality assessment of the included literature.

Findings

Main findings are summarized in Table 2 and Table 3. In Sowa et al. [10], plastic surgeons retrospectively evaluated the NAC tattoo's appearance and symmetry made with the 3D-E technique (n = 61) versus the conventional technique (n = 49) after flap-based nipple reconstruction in a Japanese facility: significantly higher ratings of appearance and symmetry were found in the 3D-E tattoos cohort. Gho et al. [17] retrospectively measured patients' satisfaction with the NAC after tattooing among 172 women in a UK facility: 70% of responders (N = 110) were satisfied. In Italy, Starnoni et al. [28] measured the satisfaction levels among tattooed women after NAC reconstruction: 92% of 48 patients were satisfied or very satisfied. In a more extensive Italian pilot study [2], an advanced practice dermopigmentator performed NAC tattoos on 169 women who underwent surgical breast

reconstruction: 90% of women were highly satisfied with aesthetic results, and 97% considered the project useful or very useful. In Brazil, Uhlmann et al. [11] tested 3D dermopigmentation technique for the NAC reconstruction, evaluating respectively the satisfaction of the professionals and the patients (N=20): the first ones perceived as “good” or “excellent” the overall aesthetics (76%) and color (72%); patients indicated as “good” or “excellent” the overall satisfaction (95%) and color (100%). In Ireland [23], a clinical nurse specialist performed NAC tattoos on women with reconstructed breast: the median score of satisfaction with the color was 4.6/5, and the mean color match between the tattooed areola and the contralateral one was 91%. In Cha et al. [6], 20 women underwent a tattoo-only technique for NAC reconstruction after an oncological mastectomy performed by one plastic surgeon in a Korean medical facility: these patients mostly showed reluctance to another operation, skin problems, collateral effects of radiotherapy and chemotherapy, smoking habit; the average overall satisfaction score was 8.1 on a 10-point scale, significantly the highest compared with the other techniques one. In one Australian cohort study [29], women who underwent NAC tattoos were asked to express their opinion about satisfaction with the nipple, as well as quality of life, sexual well-being, and other psychosocial issues, with a validated questionnaire before and after the intervention. The authors also wanted to identify any differences in patient satisfaction between those treated by the nurse practitioner (N = 169) and those by the plastic surgeon (N = 111): among responders (48%), a significant improvement was found in the patient’s satisfaction with their NAC, but no significant differences were found between clinicians. Di Censo et al. [26] wanted to determine if the likelihood of discussing options for NAC tattooing and recommending tattoo artists differed between Registered Nurses (RN) (N=43) and non-RNs (N = 25): no significant difference was found between the groups on awareness and recommendation of a tattoo artists providing a NAC tattoo. Aslam et al. [25] aimed to identify if radiotherapy exposition influenced tattoo fading among 292 women after flap reconstruction in a UK medical facility: the median time of fading was 4,5 months. 70% of the people who had radiotherapy and subsequent NAC tattoos had problems retaining the tattoo pigment and required repeated tattoo sessions. In the USA, an institutional review [13] of 539 patients who underwent NAC tattooing after reconstructive procedures showed that the tattoo-related infections were 2.2 % (n = 21 breasts), while the mean time to infection was 6.5 days; also, 85.7% of infections occurred in Implant Based Reconstruction (IBR) patients, and one-third of them had previous radiation treatment. This study suggests that previous radiation and pre-pectoral IBR are independent predictors of tattoo-related breast infection. Finally, two abstracts were included in the analysis of the results (Table 3): Rider et al. [24] aimed to determine if the type of reconstruction [Transverse Rectus Abdominus Myocutaneous (TRAM) flap reconstruction (N = 31) and Latissimus Dorsi (LD) flap reconstruction (N=93)] or the post-reconstruction RadioTherapy (RT) have any effects on the number

of tattooing episodes required to obtain a satisfactory result: no significant difference was found between the number of patient satisfied after one or more session in all groups (LD no RT, LD with RT, TRAM). Finally, one study [31] quantified changes in NAC tattoo color over time by analyzing images of women who underwent NAC tattooing (N = 71) in a USA medical facility: the length of time is inversely correlated with scores and quantitative parameters of color and shape. The authors suggest that the fading phenomenon is predictable and measurable.

Author; year; Country	Study design	Population	Methods				Adverse events	Main results	
			<i>Professionals and training</i>	<i>Time</i>	<i>Materials</i>	<i>Data collection tools/analysis</i>	<i>Endpoints</i>		
Sowa et al. (2021) JAPAN	retrospective study	3D-E tattoo (N=61) VS conventional technique tattoo (N=49)	One plastic surgeon with little training	21 months	Tattoo machine	10-points scale	Four senior plastic surgeons evaluated from pictures (1) 3D appearance (2) symmetry of NAC	NR	Higher appearance and symmetry in 3D-E tattoos.
Goh et al. (2011) UK	retrospective study	NAC tattoo (N patients = 172)	Specialist nurse tattooist	8 years	Tattoo machine	5-points scale postal questionnaire	Patient satisfaction with the NAC	local erythema (n=8); bleeding (n=8); local infection (N=4)	110 respondents; 70% were satisfied.
Starmoni et al. (2020) ITALY	retrospective study	NAC tattoo after nipple reconstruction (N patients = 48)	Surgical trainees with 20 h- training with a professional tattoo artist	2 years	NR	Questionnaire	Patients' satisfaction	scar nipple dehiscence (N=3)	92% were satisfied or very satisfied.

DiCenso and Ficher-Carlidge (2015) USA	cross-sectional study	BC RNs (n=43) VS BC non-RNs (n=25)	NA	5 weeks	NA	Online survey	likelihood of discussing options for NAC tattooing and recommending tattoo artists	NA	RNs were significantly less likely to recommend a professional tattoo artist than non-RNs
Cha et al. (2019) KOREA	retrospective study	Tattoo-only NAC reconstruction (n=20) (subgroup of 95 patients that reconstructed the NAC with other techniques)	One surgeon Training: NR	9 months	Tattoo machine	10-points questionnaire	overall satisfaction	NR	Average overall satisfaction score: 8.1/10. significantly the highest compared with that of other techniques.
Aslam et al. (2015) UK	descriptive study	NAC tattoo after flap reconstruction (N patients = 292)	BC clinical nurse specialist trained in tattooing	9 years	NR	Questionnaire	(1) Patient satisfaction (2) Relationship between RT and tattoo fading	NA	Response rate: 60% 165/173 were happy with overall appearance 70% of RT patients reported fading.

Gava et al. (2020) ITALY	Pilot experimental study	BR (N patients = 169)	Advanced practice professionals	6 years	Dermograph	Phone interview	(1) Patient satisfaction (2) Service usefulness	Minor complications (N=3) (topical allergic reaction, abrasion, and soreness)	High satisfaction of the aesthetic results (90%); the service was useful/very useful (97%).
Smallman et al. (2018) AUSTRALIA	cohort study	Nurse-performed NAC tattoo (N patients = 169) VS plastic surgeon-performed tattoo (N patients = 111) after BR	Nurse/plastic surgeon Training: NR	6 years	Tattoo machine	BREAST-Q questionnaire	Before/after patient satisfaction	NR	Response rate: 48% Higher satisfaction with NAC after tattoo. No significant difference between clinicians.
Uhlmann, Martins and Piato (2019) BRAZIL	pilot experimental study	BR (N patients = 30)	Tattoo artist	22 months	Tattoo machine	5-point-scale	Patient and professionals' satisfaction	No	Professionals: good and excellent overall aesthetics (76%) and color (72%); tattooed patients (N=20): overall satisfaction (95%) and color (100%).

Murphy et al. (2010) IRELAND	descriptive study	NAC tattooing after BR (N patients = 26)	Clinical nurse specialist	2 years	Tattoo machine	(1) Phone survey (2) computer program	(1) Patient satisfaction (2) Color matching	No	Median satisfaction score: 4.6/5; mean color match of 91%.
Weissler et al. (2021) USA	retrospective study	NAC tattooing after BR (N patients = 539)	Physician assistant or plastic surgery trained by a nurse	11 years	Tattoo machine	univariate analysis and multivariable regression model	identify risk factors for tattoo-related breast infections	Tattoo-related infections 'rate: 2.2%	85.7% of infections occurred in IBR patients RT and prepectoral IBR are independent predictors of tattoo-related breast infection.

Table 2 - Main characteristics and results of full-texts included in the review.

Author; year; Country	Study design	Population	<i>Professionals and training</i>	<i>Time</i>	<i>Materials</i>	<i>Data collection tools/analysis</i>	<i>Endpoints</i>	Adverse events	Main results
Rider et al. (2014) UK	Retrospective study	NAC tattoo after TRAM flap BR (n = 31) vs LD flap BR (n patients = 93)	Nurse practitioner Training: NR	8 years	NA	Fisher exact test	Any effects of reconstruction's type and RT on N° of tattoo session	NA	No significant difference

Levites et al. (2014) USA	Retrospective study	NAC tattoo pictures (N patients = 71)	5 medical students Training: NR	6 years	NA	Customized scoring system software	Quantify color fading over time	NA	The fading phenomenon is predictable and measurable.
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Table 3 - Main characteristics and results of only abstracts available included in the review.

Synthesis of the results

This scoping review provides immediate implications for practice, adding knowledge on the impact on patient outcomes, professionals, and organizations, as well as on the type and quality of evidence available on the topic.

The NAC tattoo completes the reconstruction process after cancer treatment. Also, it represents a stand-alone option when surgical ones are not possible. These are the cases where a risk of poor outcome is consistent, like patients with fragile and/or tight breast skin or unsuitable for local skin flap elevation. Moreover, NAC dermopigmentation can be considered by those patients who refused to undergo another surgery for various reasons (exhaustion, fear, panic) [2]. The result is evaluated as satisfying and realistic [10], even if the projection is only apparent and not tridimensional.

Nevertheless, nipples' symmetry and projection are naturally challenged by the contralateral breast changes over time and by the skin flaps or RT consequences on the treated breast [6, 10]. Another disadvantage of the technique is the color's natural fading process, which requires periodical tattoo sessions to maintain the aesthetic result. The role of RT in this phenomenon is currently not completely clear: according to Aslam et al., tattoo fading is a significant problem in RT patients [25], but Rider et al. [24] suggest that the post-reconstruction RT exposition did not influence the aesthetic result. The fading phenomenon is often reported subjectively, although it may be quantifiable [31].

The impact on professional competence

The professional training on the tattoo technique is specified in 6 papers. The issue remains variable and poorly described: in one study, a professional tattoo artist trained medical residents [28], while in another, a plastic surgeon trained a nurse [29]. Sowa et al. refined the tattoo technique, as it can be easily applied by medical staff instead of tattoo artists [10]. Nurses were the professionals primarily involved (N papers = 6), then medical staff (N papers = 4) and tattoo artists (N papers = 2). The figure of a clinical nurse specialist performing NAC tattooing was involved in 5 studies and worked in day-case or outpatient settings [17, 23-25, 29].

The impact on patient's health

The endpoints were mainly focused on the aesthetic result's satisfaction rate, which was favourable. Other Patient Reported Outcomes (PROs), like quality of life, sexual well-being, and other psychosocial issues, were evaluated by Smallman et al. with the BREAST-Q-specific module for breast reconstruction [29]; this study was the only one that used a validated questionnaire, and the only

one that compared the results before and after the tattoo. The most frequent limitations declared in the studies reviewed were the poor evaluation criteria [2] and the use of study-specific questionnaires based on previous works [10, 11, 17].

The impact on healthcare organizations

Studies described some experiences of nurse-led services [17, 23]. Several studies underline the necessity of these in-clinic services [2, 13], as NAC reconstruction represents a restoring and essential final step in the oncological care pathway [10, 17, 26]. Di Censo et al. describe the lack of standardization of tattoo services in the USA, suggesting that integrating a tattoo specialist into the healthcare team can ensure equal access to this care [26]. Even if a structured cost analysis did not emerge in the literature, some elements suggest significant savings: the Operating Room (OR) and general anaesthesia are not required for the intervention, avoiding long-time healing and control visits for dressings. Gava et al. estimate about 1,600 euros of savings, considering costs for one patient NAC reconstruction (approximately 1 hour of OR utilization, medical and nursing staff, recovery room, medical supplies, anaesthesia, and pharmacy) [2].

Discussion

According to the small body of literature, NAC tattooing represents a safe and well-tolerated technique that provides satisfactory aesthetic results. Additional research is needed to fill the knowledge gap on how this service may be provided and which outcomes it addresses. Despite the high risk of bias, some significant issues were extracted and analyzed. Further and larger studies are necessary to assess which is the best technique, the specific criteria according to which the tattoo-only approach is recommended, and eventual differences when compared with other procedures. Also, the relationship between fading and radiotherapy should be deeply understood with a more robust and broader design study. Specialist training pathways are necessary to define competencies and quality levels better. The NAC dermopigmentation needs to be provided by trained clinical specialists, aware of fragilities that can occur in women involved: low immune defences, skin alterations, chemotherapy in progress, previous radiotherapy. Evaluating costs, some considerations about professional competence may deserve more attention: involving specialized nurses instead of medical staff may produce savings and reduce waiting lists for surgeries and medical check-ups. This ultimately translates into increased productivity and workers' motivation.

Furthermore, intercepting PROs with specific and validated instruments can provide reliable evidence about a large spectrum of effects on women's lives. Body image represents a multifaceted

psychological experience comprising thoughts, beliefs, feelings, and attitudes. The related sufferings are perceived as global, and they should be identified from both a quantitative and qualitative point of view: the "Appearance-Pain" consists of the recomposed systematic view of the experimental indicators of suffering, linked to one of the dimensions of appearance [32]: this can represent a new complex outcome, that should be assessed with appropriate questionnaires, like the DAS59, also validated for breast cancer patients. Measuring the role of appearance may add more precision and personalization to cosmetic medicine, combining psychological and relational dimensions of the perceived body image. As the NAC dermopigmentation potentially implies all these aspects, it should not be considered an "extra" but part of the same restoring process involving mental and physical rehabilitation. Healthcare management is crucial in exploring the most feasible way to provide this service. Further research may explore the relationship between competence and patient outcomes: technical and artistic expertise should be combined with advanced competence in oncological care. Encouraging guides on the training curricula in medical tattooing are developing [33]: assessing the effective integration of all the competence elements ensures the highest quality service and patient safety.

Limitations

The present review has some limitations: first, only English papers were included, which may have partialized the results. Secondly, the poorness of the literature available, both in the number of studies available and in the methodological quality, cannot permit the generalization of results.

Conclusions

The tattooing of the Nipple-Areola Complex is a safe and satisfactory intervention that can finally restore the integrity of appearance for women who have faced demolitive cancer treatments, with an auspicious improvement of self-perception, anxiety, depression, sexual function, and identity role. Future studies are urgently needed to deeply understand the relationship with quality of life outcomes and assess the processes involved in this service, particularly the feasibility of nurse-led services. It appears worth exploring the appropriate research methodology for this intervention for women's health.

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Statements & Declarations

Contributions

Tiziana Livieri, Gloria Farioli, Stefania Lucchi and Monica Guberti contributed to the article conception; the literature search and data analysis were performed by Deborah Maselli and Martina Torreggiani; the first draft of the manuscript was written by Deborah Maselli and all authors commented on previous versions of the manuscript. Monica Guberti critically revised the work. All authors read and approved the final manuscript.

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Ethics declarations

Ethical approval: As this study was a scoping review, ethical approval was not required.

Consent to participate: Not applicable.

Consent to publish: Not applicable.

Chapter III

Developing a complex intervention

Submitted as:

A nurse-led multidisciplinary service for Nipple-Areola Complex Tattooing after breast cancer: reporting on a complex intervention with TIDieR analysis.

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Abstract

Background: The Nipple-Areola Complex (NAC) tattooing can restore physical and mental integrity after breast cancer, but it is not always easily accessible for women. This paper aims to report on the development of a multidisciplinary nurse-led service for NAC tattooing for women who underwent breast cancer surgery with NAC removal to allow its thorough review and replication.

Methods: The Medical Research Council's framework for developing complex healthcare interventions was followed. According to the results of a literature review, and the context analysis, an initial intervention was planned. The Template for Intervention Description and

Replication checklist was chosen to ensure the quality and completeness of the intervention description.

Results: The Breast Unit and the Research departments were engaged; three nurse-tattooists were selected; the informative material was created and shared with patients, families and local associations, involving them actively. Finally, the setting and the materials were defined. A monthly schedule of activities was set: patients with the indication for NAC tattooing were contacted by the nurse case manager. Each treatment involves 3-4 sessions, 30-40 days apart, in an ambulatory setting. It consists of NAC shaping and tattooing with a dermographer and sterile needles.

Conclusion: Implementing freely and equally multidisciplinary nurse-led clinics might provide this treatment ensuring the patient's quality of life and nurse competence. The NAC tattooing is a complex intervention that represents the final part of the breast cancer surgical care pathway.

Keywords: Medical Tattooing; Women Health Services; Breast Cancer Nursing; Complex Intervention; Oncology Nursing; Health Service Research.

Background

Breast cancer is the most frequently diagnosed malignant tumor in women [1]. When surgical treatment is indicated, it can affect quality of life even years later [2]. It is well known that many patients experience difficulties related to the complexity of reconstructive treatment with the removal of the Nipple-Areola Complex (NAC) [2, 3]. The loss of harmony in the body image's perception can compromise identity and relationships with others [4, 5]. Providing a multidisciplinary nurse-led service for NAC tattooing as the final part of the breast oncological clinical pathway might improve women's physical and psychological rehabilitation and wellness. The NAC dermopigmentation reconstructs the NAC appearance [6]. International evidence suggests that dermopigmentation is a satisfactory and well tolerated nonsurgical technique, with low complications, costs, and waiting times [7, 8]. The tattoo can be performed alone or with other reconstruction techniques [9-11], under local anaesthesia. Moreover, it represents the only possible option in case of some contraindications, such as damaged tissues, comorbidities, anxious states related to past hospital experiences [8, 12]. Initially introduced by Rees [13] and recently refined [14, 15], the steril/semi-sterile technique is performed by a specifically trained

professional through the introduction of bioabsorbable pigments into the superficial papillary dermis with a disposable needle, through a demographer or manually [16]. The lack of in-clinic NAC tattooing services is a barrier to equal access to this type of care. In many countries, this technique is usually performed by professional tattoo artists [17], with considerable costs for patients. Literature shows variability in professional and management aspects according to healthcare contexts [17, 18]. Establishing the appropriate competence and the replicability of NAC tattooing in-clinic services represents a challenge for research, as also understand the relationship with quality-of-life outcomes and assess the feasibility of nurse-led services [18]. The NAC tattooing is an example of a complex intervention in healthcare: following the definition, the complexity of an intervention is determined by its properties and by the number of components, structures, and roles involved, as well as the expertise and skills required [19]. Identifying the context of applicability and the appropriate outcomes and assessment processes is essential. To our knowledge, studies have yet to apply this framework in developing and evaluating such interventions. The purpose of this paper is to report on the development of a multidisciplinary nurse-led service for NAC tattooing for women who underwent breast cancer surgery with NAC removal to allow its thorough review and replication.

Methods

The framework of the Medical Research Council (MRC) for developing and implementing complex interventions in healthcare was chosen to achieve the objective, specifically the first of the following phases [19]: (1) development or identification of the intervention; (2) feasibility; (3) evaluation; (4) implementation. These methodological steps will be crucial in answering our research question: how can an NAC tattooing service be developed and adapted to the local healthcare context? The other phases will be assessed in future studies. This flexible model permits beginning research projects at any point and revising previous phases and elements if uncertainties remain unresolved. Some core elements are shared: context analysis, developing and refining program theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and economic considerations. The setting of the study is Santa Maria Nuova Hospital of Azienda USL-IRCCS di Reggio Emilia. We transferred the phases into WPs. The WP1 is the object of this report and presents the first development phase. It is composed of three steps:

- Step A: this step aims to examine the evidence available about the NAC tattooing reconstruction after breast cancer surgery: the grounding literature exploration was synthesized with a scoping review.
- Step B: it aims to identify theories, context elements, and part of interests in developing the intervention. The context examination was performed by sharing moments with key stakeholders, such as patients, associations, families, and professionals. Patient and public involvement are crucial to collecting information about the implementation context of a co-designed project and promoting participation through meetings and events. Identifying professionals, healthcare services, materials, and settings was planned.
- Step C: this phase aims to develop an initial plan of activities by integrating collected evidence (step A) and context analysis (step B). The following elements were identified: activities scheduling, waiting list management, materials storage, ordering and tracking, personnel management, documentation and procedure development, and collection of photographic/audio-video materials.

Moreover, the Template for Intervention Description and Replication (TIDieR) will describe the intervention in detail to ensure the quality and completeness of the description. This validated tool is needed as it helps capture the accurate composition and interacting features of a complex intervention with reliability [21]. At each stage of the process, all activities were continuously monitored and refined. The WP2 will be started in a further study, and it consists in the feasibility study: it aims to test the planned intervention by assessing the preliminary organizational feasibility, with an initial focus on safety, overall satisfaction, and economic evaluation.

Findings

This report describes the activities conducted in the development phase of the ARCADE service.

WP1 - Step A: Evidence about NAC tattooing

The scoping review results [18] confirm that NAC tattooing is a safe and satisfactory intervention that can finally restore the integrity of appearance to women who underwent demolitive cancer treatments, improving their quality of life with promising cost-effectiveness. The paper points out that professional training on tattooing techniques is

variable and poorly described: nurses were the most involved, followed by medical staff and tattooists. The endpoints explored in the literature focused mainly on the satisfaction rate of the aesthetic result. Finally, the most frequent limitations were poor evaluation criteria and the use of study-specific questionnaires based on previous work. The studies described some experiences of nurse-led services. These findings present a relevant field of research and allow us to orient resources and plans for a local intervention development.

WP1 - Step B: The context analysis

As the context can determine the success of a new service introduction, we focused on these actions.

Understanding the local regulatory framework

In the Italian universalistic healthcare system, the tattooing for medical purposes is performed on people who need to cover pathological skin conditions, restore the appearance of healthy skin, or as an adjunct to reconstructive surgeries [16]. In this case, it can be a phase of the medical procedure that intervenes downstream of the diagnostic-therapeutic course to restore a balance and recover, psychologically, the patient's well-being and an excellent final aesthetic outcome, according to the complete concept of health: a full condition of life from the individual, economic and social point of view. The medical tattoo of NAC is the only one legislatively regulated [22] and included in the Essential Levels of Care (and therefore supported by the National Health Service).

Identification of health services and professionals

We worked on building a solid core competence integrated within the services: the Research & EBP Unit of the Health Professions Department, the Scientific Direction of the Cancer Research Institute, and the Integrated Breast Unit were involved for each level of responsibility. Three motivated and trained nurses were chosen to lead the service with the collaboration and supervision of the breast unit medical staff through an internal public selection. The dermopigmentation will be performed mainly by one highly specialized nurse with extensive experience in women's oncological surgery. The scientific and management aspects of the research were handled by the Research & EBP Unit.

Patient and Public Involvement

We created a brochure that provides patients with necessary information about the treatment. We presented the project to patients, families, citizens, and local associations. In 2022, we organized a competition among residents to propose the name of the new clinic, with a large and enthusiastic participation. One hundred forty-two name proposals with motivations were collected, all dense of meanings evoking concepts of renaissance and harmony comeback. The winner's name was ARCADE: the word reminds the service activities ("Ambulatorio Ricostruzione Capezzolo Areola DErmopigmentazione). The name is also similar to "Arcadia" a famous region celebrated in Greek mythology as an unspoiled place of harmonious wilderness. Stakeholders like patient associations were essential in raising awareness and spreading evidence-based information among the community.

WPI - Step C: The planning of activities

Combining scientific evidence with local considerations, we started the development of an initial intervention. As each treatment involves about 3-4 sessions 30-40 days apart, we proposed that the clinic activities would be done monthly, with an initial patient group meeting to introduce the treatment and clarify any doubts. Regular briefings and debriefings were planned to share procedures, management aspects, and any issues that would have arisen. The following logistical and technical aspects were defined and shared:

- Population: the intervention is dedicated to adult women who underwent mastectomy with NAC removal within six months, with medical indication to the NAC dermopigmentation.
- Setting: the clinic activities will be carried out in ambulatory, day-case settings in Santa Maria Nuova Hospital of Reggio Emilia.
- Contact: eligible patients would be contacted individually by the breast nurse case manager to agree on the date and time of the session.
- Documentation: instruments for tracking and ordering materials, waiting list management, and clinical documentation were prepared.

It was expected that for each of the first sessions, it would be possible to treat patients who need one bilateral and one unilateral tattoo or up to three unilateral ones. The procedure of the intervention with timing and materials information was shared.

The planned NAC tattooing intervention

The intervention is described with the TIDieR Checklist in the Appendix A. The technical procedure and training are based on the best scientific evidence and valid and well-established referrals in this field [23]. Thanks to a local cream anesthetic, the treatment is painless and odorless. The tattooing with natural pigments does not interfere with instrumental examinations or breast implant replacement. The bioresorbable pigments made the color naturally and gradually fade (in the days following the session, about 30-40%). Natural pigments differ from artistic pigments precisely because of their reabsorption properties in the body over time, which also allow, thanks to periodic sessions, to give conformity to the changes brought about by skin aging. The dermopigmentation can also be performed on any previous scars in the areola-nipple area by including them in the tattoo design. The reproduction of the areola-nipple complex will be done with a 3D (light-dark) effect technique by inserting bioresorbable pigments into the epidermis with disposable needles. The instrument used to carry out this technique is the dermograph. This comprises a central body, which allows the needle oscillation speed adjustment, a handpiece, and sterile disposable needles. Considering that the third session best fixes the color, an annual appointment for a touch-up will be necessary. In the first dermopigmentation session, the nipple-areola design (color, shape, and overall appearance of the areola) is created. During the 30 minutes necessary for the anesthetic cream to work, an individual interview is conducted to clarify all aspects of the procedure. The tattoo session lasts, on average, one hour. It has been pointed out that no preparation is necessary before the session, only a few precautions to be followed after the treatment: upon its completion, the treated area should be cared as any wound. Nurses will leave an oily gauze in place to be removed about 3 hours later. At home, patients should perform regular hygiene of the new areola with mild soap and water, without rubbing but dabbing it. Applying an emollient cream for 3 to 4 days, 1 or 2 times a day, and as needed is recommended. In the following days, small scabs may form, which should be left in place until their natural fall, which will occur approximately after 10 to 15 days; this expedient is essential to prevent local infections and to allow the pigment to fix itself at its best. During this period, it is necessary to avoid swimming pools, saunas, steam baths, intense sports activities, laces, synthetics, sun exposure, and parfum use.

Discussion

This paper reports on the development of a multidisciplinary nurse-led service that provides NAC tattooing reconstruction after cancer surgery. The chosen methodology was appropriate, as it permitted us to understand which factors determined the success or the

failure of ARCADE in the local context. Evidence-based healthcare is known to be a cycle process informed by the best available evidence, the context in which care is delivered, the individual patient, and expertise of the health professional [24]. However, where evidence is sparse, more inclusive, and less traditional, methods can allocate value and relevance to findings, as they can inform healthcare decisions and resolve many important evaluation questions [19]. Hence, we have seen that the tailoring to the specific context is essential to address a real health need appropriately. This experience promoted multidisciplinary health research on innovative care models and services in oncology, focusing on cancer survivors' quality of life and economic aspects. The project has a potential positive impact on professional competence, patients' quality of life, and organization. The selection process of the nurse tattooists was completed assuming that the expertise of health professionals is the key to guarantee the quality and feasibility of the intervention. Being a professional in the field of medical dermopigmentation means not only knowing the techniques of color design and use but also having a broad and in-depth view of dermatologic, oncologic, and surgical elements [25]. In addition to the technical aspect, they should focus on the therapeutic relationship established by elaborating on body image and identity after cancer, as included in a referral team on decision support and territorial services. Nursing competence in this field should also include patient counselling about body image, scar management, identity role issues after cancer, decision support on postmastectomy options, and quality of life [26]. The definition of a skills' profile, the competence maintaining, and the specialized professional support network (e.g., dermatology, radiology) will be the elements of future research refinement.

We cared about providing fulfilling information and safety along all the activities, collecting feedback, and monitoring complications. The intervention's impact on patients varies from cosmetic outcomes to satisfaction and quality of life, that brings strong significance to implementing services like this that restore psycho-physical integrity. The following steps will provide accuracy in the quality assessment of the intervention and will focus on systematically evaluating the quality of life aspects implicated in NAC tattooing. The preliminary phases of WP1 are continuously implicated in this evaluation: as we have seen, the context is determinant: the stakeholder feedback and the resource evaluation may be decisive in the success or failure of an intervention. This will be monitored in further evaluations, and the following elements will be defined: tools for intervention prescription and accountability, structured cost-effectiveness evaluation, and staff management.

This research presents some limitations: first, the results are not generalizable, as they refer to the context of application; second, they are to be considered preliminary and referred to activities description and processing. Despite the considerations above, this project on breast cancer care and survivorship highlights some strengths, exploring with reliable methodology fields of advanced care nursing in leading new quality-of-life services in oncology care that is valuable and worthy of exploration. To our knowledge, this is the first report that used the TIDieR checklist to describe a NAC tattooing service as a complex intervention, a fundamental step to ensure transparency and replicability in health service research. More structured specialist training pathways are necessary to better define competencies and quality levels. Studies highlighting the multiple positive impacts will be helpful: professionals might benefit from this experience in growing competence, satisfaction, motivation, engagement with continuous care, and teamwork. Finally, the organization will benefit from this implementation, improving health outcomes affordably and cost-effectively.

Conclusion

Providing a NAC tattooing service after breast cancer is an intervention that closes the circle of the oncological care pathway. Implementing these services has an extensive meaning for women's global health, promoting organizational efficiency, safety, and nurses' professional value. A valid methodological referral is essential to assess a complex intervention's development and piloting. The next steps are required to systematically evaluate the quality of life issues implicated in NAC tattooing and the sustainability of this multidisciplinary nurse-led service.

Declarations

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and materials: Data supporting the conclusions presented in this article have been reported in the article. The details of the scoping review are published elsewhere [18].

Competing Interests: The authors declare that they have no competing interests

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Author Contributions

M.G. and D.M. contributed to the article conception; M.G., D.M. and M.T. conducted the data analysis, D.M. and M.T. contributed in manuscript writing. All the authors commented on previous versions of the manuscript and critically revised the work. All authors have read and agreed to the published version of the manuscript.

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Chapter IV

Evaluating a complex intervention

4.1 Introduction

As discussed in the previous chapter, the implementation of this service can have significant implications for women's health worldwide, promoting organisational efficiency, safety, and the professional value of nurses. When developing and piloting a complex intervention, it is essential to use a valid methodological approach. Although reducing health disparities is a priority, addressing their complexities remains challenging, particularly in breast cancer survivorship care [1, 2]. Involving patients, their families, and communities in addressing this challenge is crucial [3]. Mahony et al. demonstrated that early contact with a specialist breast cancer nurse positively impacts patients, health services, and the healthcare system, leading to substantial net savings [4]. The organization of care services can influence the magnitude of these effects and should be optimized according to patients' needs and the local healthcare context. The study conducted in WP2 seeks to evaluate the feasibility of establishing the ARCADE clinic. The intervention analysed was described in through the previous chapter.

4.2 Methods

Study design

To accomplish the overarching objective outlined above, the Medical Research Council (MRC) framework for the development and implementation of complex healthcare interventions was selected [5]. The four phases of the methodology are as follows: (1) development or identification of the intervention, (2) feasibility assessment, (3) evaluation, and (4) implementation. Further details regarding the initial phase are available in a prior publication [6]. This section delineates the second and third phases of the framework as applied to this project. Complex interventions comprise multiple interacting components and are commonly implemented within service delivery contexts across diverse fields, such as palliative care [7], rehabilitation, and mental health [8]. It is crucial to understand the barriers and facilitators related not only to the characteristics of the intervention, but also to the individuals involved, in order to ensure successful implementation [9].

The application of NAC tattooing within an oncological context exemplifies a complex intervention in healthcare, with its impacts evaluated across patient, professional, and organizational levels. To assess the feasibility of a nurse-led NAC tattooing clinic, we implemented the ARCADE_M study, an observational, single-centre, mixed-methods study. Its protocol was approved by the Area Vasta Emilia Nord ethic committee N° 2024/0133222, on 09/10/2024, and it is registered in Open Science Framework: https://osf.io/evrhc/?view_only=fe0aa5e7a9424def9177aa7376d8938c.

Specific outcomes

The ARCADE_M's goals were: to assess the organisational sustainability of the nurse-led NAC tattooing clinic (Endpoint 1); to evaluate the cosmetic outcome of the NAC tattoo (Endpoint 2); to explore the professionals' perceptions on their involvement in the NAC tattooing clinic (Endpoint 3); to explore the lived experiences of the tattooed women (Endpoint 4). This paper presents the results related to endpoints 1 to 3. Endpoint 4 will be discussed exhaustively in a separate report.

- Endpoint 1: activity and process data of the ARCADE clinic were analysed retrospectively.
- Endpoint 2: a panel of experts analysed the photographs of the tattooed NAC according to objective criteria (symmetry, colouring, 3D effect).
- Endpoint 3: a qualitative study with semi-structured interviews was implemented to explore the perceptions of the healthcare professionals regarding their involvement in the ARCADE clinic.

Setting

The study's setting is the Breast Surgery/Plastic Surgery Unit of the Azienda USL - IRCCS of Reggio Emilia, specifically the ARCADE nurse-led clinic of the plastic surgery service. Participants were interviewed at the Research, EBP, and IRCCS Unit, Health Professions Directorate of the Azienda USL - IRCCS of Reggio Emilia.

Study population

Endpoint 1: data regarding activities and processes were collected from January 2023 to August 2024, when 62 patients were treated with NAC tattooing at the Azienda USL – IRCCS di Reggio Emilia. Specifically, we collected retrospective data of patients that

fulfilled the following criteria : (1) adult, (2) being able to speak and write in Italian; (3) willingness to participate in the study and sign written informed consent; (4) have undergone oncological breast surgery with removal of the NAC; (5) have received NAC tattooing.

Endpoint 2: starting from the cohort described above, we included patients who had completed the treatment at the date of study submission (6) and (7) agreed to contribute with the photographs of their NAC.

Endpoint 3: we included health professionals involved in the provision/evaluation of this service. They are specialists with experience in breast surgery or breast reconstruction, professionals with training and experience in the NAC tattooing, clinical coordinators or managers of health care facilities involved in the service development and management.

Data collection

Data collection was conducted by appropriately trained professionals and research nurses (DM, MT), and registered on the eCRF. Age, surgical NAC reconstruction, monolateral/bilateral tattoo, were patient-related variables collected. The main indicators concerning the Endpoint 1 included the number of tattoo treatments completed/not completed per person, the number of sessions required per person, adverse events, procedural pain, duration of sessions, not-standard adjustments to the procedure, pigments and needles used. For the Endpoint 2, the available photo sets were considered. Those that permitted comparisons (pre/post-treatment, or NAC comparisons), through at least one of the quality indicators (color similarity, symmetry, 3D effect), were included for the blind evaluation. The expert panel consisted of the nurse tattooists (TL, GF, SL) and two nurses PhD students (DM, MT), in order to allow for fairness and technical competence. For the Endpoint 3, the principal investigator (DM) contacted professionals who met the eligibility criteria by email, informing them about the study and proposing their participation. The interested professionals met the principal investigator and received a detailed description of the study. Those willing to participate were included by signing a consent form. Individual interviews were audio-recorded, transcribed verbatim and immediately deleted after transcription. Interview transcripts were stored in pseudo-anonymised form under the responsibility of the principal investigator. Two nurses PhD students (DM, MT) trained in qualitative research conducted the interviews that followed these key-points: first contact with the clinic and expectations; factors that acted as barriers and facilitators in the activities

of the clinic; future challenges and opportunities; the role of the nurse in this treatment; the meaning of this clinic within a clinical pathway.

Data analysis

The Endpoint 1 involved the analyses of the frequencies and percentages for process and overall activity data, and by assessing procedural timeframes and costs. The Endpoint 2 involved the descriptive analyses of data regarding the quality of the cosmetic outcome expressed by the expert panel on a 5-points Likert scale. Qualitative findings related to Endpoint 3 were generated through a framework analysis based on the topics discussed in the interview [10] [11]. Three independent researchers (DM, MT, VS) read and familiarized themselves with the interviews, generating initial codes. In a second phase, the codes were shared and discussed until an agreement was reached, after which the research team defined the codes and began generating initial themes. Using the constant comparison method, sub-themes and themes were identified. All analyses were performed in Italian, and the results were translated into English. Methodological rigor and fidelity to the data were pursued through various strategies. The thematic analysis was conducted according to the planned methods: the research team was familiar with qualitative analysis and cancer care. The COREQ criteria for reporting qualitative research have been followed [12]. Reflexivity was considered by engaging in ongoing researchers' self-reflection, acknowledging their influence on data collection and interpretation [13].

4.3 Results

4.3.1 Organizational sustainability

This paragraph presents the data regarding the activities and processes of the ARCADE clinic, whose activity volumes are illustrated in the table below (Table 1).

2023		
New patients	Annual follow-up tattoos	Clinic days
44	/	51
2024		
New patients	Annual follow-up tattoos	Clinic days
28	24	40

Table 1- ARCADE clinic activities for 2023 and 2024.

Thirty-three women were included in the retrospective analysis (Fig. 1). Table 2 describes the main characteristics of the cohort: monolateral treatments on previously reconstructed nipples were the most frequent.

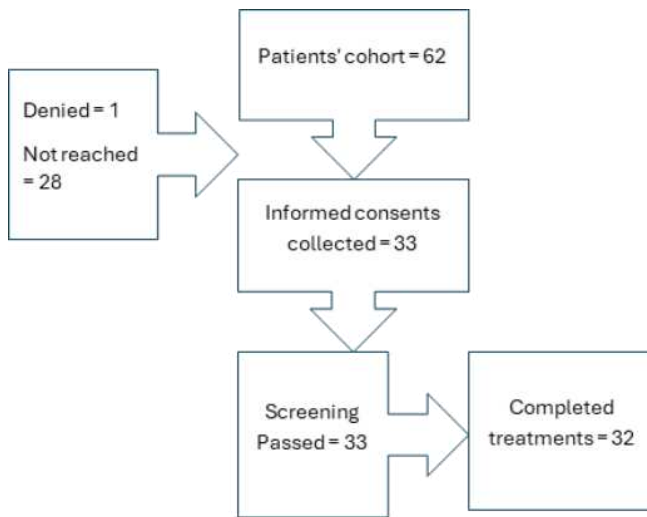


Figure 1 - Study participants and screening process.

Age range (mean age: 55)			
< 50		50 – 59	> 60
10		11	12
Left	Right	Bilateral	NR
18	11	4	0
Reconstructed NAC		No reconstructed NAC	NR
19		7	7

Table 2 - Sample characteristics.

Data presented in Table 3 show that 90% of the sample completed the treatment in 3 sessions, which is the standard of the procedure. Of the remaining 10%, two participants skipped the third tattoo session because the color was already fully and satisfactorily pigmented in the area, with less fading than expected. One participant was not tattooed at the first appointment because of a suspected allergy during the initial assessment, confirmed by the allergologist. The 100% of the sample gained a satisfactory cosmetic result following the correct post-treatment care, without adverse events, or other complications like excessive color fading or shifts.

Process	Sessions for each patient			Specialistic referrals		Post-treatment indication adherence	
	<3	3	>3	Yes	No	Yes	No
	3	30	0	2	0	32	0

Outcome	Adverse event	Unpredicted color shift	Ecessive fading
		0	0

Table 3 - Process and Outcome indicators of activities.

Session duration and the dressings used were standard. The pigments are labeled with numbers from one to nine. Table 4 shows that the color blend applied for the areola were mostly the same for every session type. The color blend used to pigment the nipple differs from the one used for the areola. All the procedures were performed using three needle types, that differed in size and function, defining details or shades. Procedural pain was measured with the Numerical Rating Scale (NRS). 79% of the reported NRS scores ranged from 0 to 3.

Intervention type	Mean Duration (Min)	Top 3 areola pigments	F		Top 3 nipple pigments	F		Needles	F	Dressing	NRS scale (range)	F
First session (N = 32)	140 (BL)	1	2	7	16	7	31	Gauze and Plaster	0-3	10		
	100 (ML)	5	1	8	8	9	31		4-6	4		
		7	12	9	5	3	22		>6	1		
						NR	1		NR	17		
Subsequent sessions (N = 62)	90 (BL)	1	4	7	36	7	57	Color's surplus application	0-3	24		
	60 (ML)	7	2	8	26	9	43		4-6	5		
		5	23	9	10	3	33		>6	0		
						NR	6		NR	33		
Annual follow-up session (N = 4)	60	1	2	7	2	Color's surplus application		0-3	3			
		5	2	9	2			4-6	0			
		7	2	NR	1			>6	0			
		NR	2					NR	1			

Table 4 - Data from the intra-procedural sheet: timing, materials, and pain level.

4.3.2 Tattoos' quality evaluation

A set of photos was available for 30 patients. Eight sets were excluded because they did not permit comparisons (pre-/post-treatment, or NAC comparisons) through at least one of the quality indicators (color similarity, symmetry, 3D effect). Of the 22 sets included in the analysis (55 images in total), 47% were collected in the first tattoo session: 14 before the tattoo (T0) and 12 immediately after it (T1). In the second session, 28% of the photos were captured: 15 photos of 30-gg tattoos (T2) and 13 taken immediately after the tattoo (T3). In the third session, 18% of the photos were collected: 5 photos of the 60-gg tattoos (T4) and 13 taken immediately after the tattoo (T5). 7% of photos were captured in the annual follow-up: 2 photos of 1-year tattoo (T6) and 2 taken immediately after the tattoo (T7). As few photos were retrieved, we decided to analyze data anonymously, prioritizing the impartiality of the panel quality assessment over statistical correlations analysis. As evaluated by the experts and illustrated in more detail in Table 5, the cosmetic outcome of the reconstructed NACs showed very good quality, with 4,7 medium score for color similarity and symmetry, and 4,8 for 3D effect. All the photos' sets allowed for evaluation of the 3D effect, while five photo sets did not permit evaluation for color similarity and symmetry.

ID	First session		Second session		Third session		Annual follow-up		Expert panel cosmetic quality evaluation (mean scores from 1-5 Likert scale)		
	T0	T1	T2	T3	T4	T5	T6	T7	Color similarity	Simmetry	3D effect
a	x	x							4.4	4.8	5
b	x	x							4,5	4,7	4.8
c	x	x							5	5	4.8
d	x					x			5	5	4.8
e	x	x			x	x			4.2	4.2	4.8
f	x	x	x	x					4.2	5	4.8
g							x	x	4.8	4.6	4.6
h			x	x					4.2	4.6	5
i	x	x			X	X			5	4.6	5
j	x			x		x			4,7	4.8	5

k	x					x			NA	NA	4.8
l			x	x					NA	NA	5
m	X	X							5	4.6	4.2
n	X					X			4.4	4.8	5
o			X	X	x	x			5	4.6	5
p			x	x					4.8	5	5
q	x	x							4,5	5	4.6
r							x	x	NA	NA	5
s	x	x		x					NA	NA	5
t		x	x	x					5	4.6	5
u		x	x						NA	NA	4
v	x	x							5	4,7	4.2
TOTAL									Overall medium scores		
	14	12	7	8	3	7	2	2	4.7	4,7	4.8

Table 5 - Cosmetic outcome evaluation from photos 'sets.

4.3.3 Qualitative findings

Five professionals (two nurses, one surgeon, and two managers) involved in the ARCADE clinic were interviewed. The analysis of the transcriptions resulted in four thematic macro-areas: "The value of the clinic", "Barriers to the service's development", "Facilitators", and "Challenges and future needs". More details and exemplary quotations are illustrated in Table 6-9.

The value of the clinic

The NAC tattoo service was broadly acknowledged for aiding patients in restoring their self-image and social integration. Participants felt that, in addition to conventional medical treatments, it tackled the psychosocial aspects of cancer recovery. They believed the service offered a holistic and emotionally meaningful support for patients within the cancer care journey, which also motivated providers.

Barriers to the service's development

Participants highlighted that limited resources, in terms of staffing and funding, constituted a fundamental constraint. They also acknowledged that lengthy logistics and informatics interventions initially delayed the implementation of the initiative. Regarding teamwork, although initial enthusiasm was observed, participants emphasized the subsequent need for increased collaborative efforts and improved coordination. Additionally, managerial changes during the implementation period contributed to the destabilization of the original vision.

Facilitators

According to the interviewees, the initiation of the service was facilitated by the team’s attitude, which was marked by strong dedication, motivation, and a shared commitment to the project's goals. The service received support at multiple levels from various stakeholders. Notably, the formal recognition of NAC tattooing as a national essential level of care within the public health system was highlighted. Having basic education on sterility concepts, knowledge of the breast cancer care pathway, and the presence of a specialized nurse were key factors that allowed the service to begin. Additionally, ongoing support and recognition from healthcare facility management and local patient associations played crucial roles. Lastly, the patients' strong confidence in the professionals provided essential support, and the team's existing expertise was a significant advantage in making patients comfortable and earning their trust.

Challenges and future needs

Participants faced challenges, including developing a data-driven model for assessing workflows and quality standards and integrating the service into institutional pathways through formalization. Managing patient waiting lists and evaluating staff competencies are also crucial. Interviewees suggested that scientific validation and formal recognition of NAC tattooing training, currently offered by external companies without official status, would be helpful. For sustainability, managers should maintain a trained, motivated staff while balancing workforce size, skills, and the service’s specialized needs.

Macro-theme	Theme	Exemplifying quotations
The value of the clinic	Supporting self-image recovery and societal reintegration.	<i>"(...) and therefore within a Scientific Institute for Research, Hospitalization and Healthcare in the oncology field, it is certainly a path that manages to overcome even the traditional boundaries of prevention, diagnosis, and treatment: it proceeds with activities that address psychosocial issues, because the</i>

		<i>acceptance of oneself also allows women to work better, integrate into the community, and have a more satisfying life." (P2).</i>
	Providing a comprehensive and emotionally significant care pathway.	<i>"Being able also to offer the reconstruction with nipple-areola tattooing gives an image of oneself and therefore the importance of being able to follow them throughout the entire journey, which is not limited to a surgical intervention, but there is also an aspect of care that continues until reintegration into society and the self-image of the person." (P1).</i>
	Building resilience through positive health impact.	<i>"It has been challenging because it requires commitment and attention, but I think it is worth it. Even when one feels a bit tired, thinking about the project and its goal, the energy comes back (...)" (P3).</i>
	Responding to a fundamental health need.	<i>"Everything started from the need to provide a complete response to patients who have undertaken a breast reconstruction journey (...)" (P5). "The most emotional feeling linked to the clinic is a sense of great necessity and value of this clinic (...)" (P1).</i>

Table 6 - Themes and quotes related to "the value of the clinic".

Macro-theme	Theme	Exemplifying quotations
	Organizational limits	<i>"Making choices means taking away from someone to give to someone else... and if today we decide to invest in 5 people within the clinic, it means that another five people are not dedicated to other areas, such as chronic conditions, fragility, urgency, and other aspects." (P1).</i>
Barriers to the service's development	Difficult teamwork	<i>"To be able to realize this clinic, it takes not only interest but also the willingness to put in the effort: putting in the effort means building, writing, and discussing, calling because otherwise, if we leave it to the individual (...), there is a real risk that these projects will end up forgotten (...)" (P1).</i>
		<i>"(...) the initial problem was coordinating the activity because we are all very busy, but it was a project that also went a bit in fits and starts (...)" (P5).</i>
	Uncertainties	<i>"When trying to provide an organizational response to professionals who have already started the activity with other figures, starting again from that point is never simple because those who carried it out until the previous day might have had a vision that is not necessarily the vision of those who take over" (P1).</i>

"(...) some initial obstacles, going back to the question, highlighted the need to understand how to frame it (...)" (P5).

Table 7 - Themes and quotes related to the "barriers to the service's development.

Macro-theme	Theme	Exemplifying quotations
Facilitators	A resilient team	<i>"A great strength that I found in the planning or in continuing the work that had already been started is a very willing group (...)" (P1).</i> <i>"(...) it was the goodwill of the people, the desire to reach the goal and (...) but primarily the spirit of volunteerism that was present from figures (...) who later took on the more operational part without whom we could not have thought of starting" (P5).</i>
	Multi-level support	<i>"The other great added value is that within the construction of this clinic, an organizational research project is included, in any case, a doctoral path, which without a doubt is providing significant support in terms of the activities carried out but also in terms of the method to reach what is the future and not just the opening of the clinic" (P1).</i>
		<i>"(...) having had real support that allows us to provide the service itself, this is the basis, because if it had not been within the LEA (essential levels of care) at this moment with the critical issues in the national health system beyond the project that may be valid and beautiful to meet a need of women, but if it had not been within the LEA, we would probably have had to make different choices and therefore that" (P2).</i>
		<i>" (...) and also, the recognition by the entire management of the importance of the project precisely to respond and complete the woman's journey within our structure" (P2)</i>
Competence building		<i>"(...) the volunteer associations that have been fundamental in these years to keep us going" (P4).</i>
		<i>"Certainly having already training on what a sterile field means, what the whole surgical part means, of the path certainly made (...)" (P3).</i> <i>"I must acknowledge in particular the training that had already been cultivated in previous years (...) it was a godsend because it allowed us to say we already have competence and from there we start, rather than having to create everything from scratch" (P5).</i>

Table 8 - Themes and quotes related to the "facilitators".

Macro-theme	Theme	Exemplifying quotations
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	Organizational challenges	<p><i>"The other challenge is the data analysis, so the competence of colleagues, not only those who do research but also those who work, to be able to read a data modification and then maybe modify the organization of the clinic, making it not static, and understanding if the way we have organized it so far is a method that can work, be sustainable over time, and effectively respond to the needs of women, or if women need something else first, something else later" (P2).</i></p>
Challenges and future needs		<p><i>"(...) It is obvious that these are trainings that are not yet really in the healthcare sector; they are managed by external companies that are often also the producers of the equipment, rather than the pigments, and therefore, we must also find compatibility, understand how to carry out training that can then be certified as truly recognized training, as recognized by the professional and scientific community" (P2).</i></p>
	Professional challenges	<p><i>"(...) there is also a creative dimension to which a person who dedicates themselves to this type of activity must see if there is the attitude and if there is also the spirit to get involved to try to take steps that then become professionalism and therefore identify the motivation, do a moment of inner verification if there is this attitude and then verify the results with a dedicated training path that allows both those who learn and those who must then somehow authorize the activity and make it institutional because that is a step that makes us all responsible when after creating the request you must also propose the offer you must absolutely be able to provide services with a minimum that must be guaranteed to everyone of quality (...)" (P5).</i></p> <p><i>"So, we must mediate between extreme competence and the ability to carry on, so, in my opinion, the next challenge we have is to find a balance between optimizing competence and maintaining the possibility of offering the service (...)" (P2).</i></p>

Table 9 - Themes and quotes related to the "challenges and future needs".

4.4 Discussion

This study aimed to assess the feasibility of an NAC tattooing clinic for women who have undergone surgical treatment for breast cancer in Italy. While the central methodology employed complex intervention evaluation, specific goals were achieved to gain a clear picture of the intervention's feasibility, including organizational sustainability, cosmetic outcome, and professionals' experience. The relevance of this research lies in its rigorous and innovative approach to the topic, which gains solidity from previous phases [6], maintaining coherence with its vision. Moreover, mixed methods enriched the evidence on the multi-level impact of NAC tattooing. In the following paragraphs, we will discuss the main results of ARCADE_M's three endpoints reported in this paper.

Endpoint 1 assessed organizational sustainability: the activity has a standard character, with stable procedural times and predictable material usage. All participants achieved satisfactory results, demonstrating high tolerability and compliance without any complications. These data align with the overall workflow, where the number of 2024 sessions is more stable compared to 2023 (Table 1): organizational and procedural stability, as well as scheduling optimization, reflect the comparable number of treated women. Nevertheless, several factors contribute to the planning of activities. Three professionals were engaged in each intervention (due to training needs before reaching autonomy), working outside ordinary working hours (4 hours). Human resources issues limited the flow of activities, as did the limited access to the clinic (only one day a week in the afternoon). In addition to these actionable barriers, the treatment structure, which requires at least three months to be considered complete, impacts the appointment schedule. Moreover, the number of annual follow-ups, which is regarded as replicable with no limits, will systematically grow, overlapping with new patients, if the organizational capacity remains unaltered. The number of new patients in 2024 (N = 28) is fewer than in 2023 (N = 44), as the 2024 touch-ups performed were 24. On the other hand, choosing to prioritize new patients' interventions will increasingly delay the annual tattoos: in 2024, 16 planned annual tattoos were postponed in 2025. These data show how this trend can be initially balanced, but they also warn us about how these factors firmly influence the possibility of providing complete and timely care.

The experts' panel evaluation of the treated NACs indicates high-quality scores for NAC similarity, symmetry, and 3D effect. In the absence of a specific and widely acknowledged instrument for quality evaluation in this field, a Likert scale was used. It was noted that symmetry was not always applicable in the evaluations, for example, when breasts with reconstructed NACs are already evidently asymmetrical. Alternatives like NAC shape similarity may be a helpful indicator. Regarding color, human evaluation cannot be as precise as AI comparison. While some inspiring experiences are reported [14] [15], questions about the everyday applicability, costs, and the absolute necessity for this measurement are to be considered. Although the cosmetic outcome must be evaluated for quality auditing and continuous improvement, an essential part of this is the woman's perception, which is intimate and can change over time. In other words, pigment composition and its normal fading are worth measuring. However, personalization in every session and biological variables that can influence color uptake must be considered. Another issue is that the actual evaluation of the color fix can be done after 30 days, when the skin has healed and the excess color has faded. After the third session, the patient was unable to attend the clinic for the final evaluation. For a comprehensive assessment, this should be considered, but with consideration for patient burden. Easier contacts and access may be considered.

The themes we developed from the interviews, which are crucial for this field comprehension, involved in the NAC tattooing, were very informative by integrating quantitative data in this research. Organizational limitations related to logistics and human resources were the primary barriers, as well as poor coordination within the team and uncertainties about the service's vision and identity. Despite these issues, the resilience of the nurse tattooists in motivation and dedication was the main strength of the project's progress. The support granted by medical and health professions management integrates that of the associations, research, and patients, who perceived the professionals' competence and ongoing education within the practice. The value of the clinic emerged clearly from all the interviews: the intervention promotes self-image recovery and societal reintegration, providing a comprehensive and emotionally significant care pathway that addresses a health need. Its relevance is matched by its overall significance in benefiting breast cancer patients and survivors. Moreover, it is important that they can access the service without facing a heavy financial burden, within a healthcare framework that supports this equally. It represents a crucial point to be shared in the scientific and civic community.

4.5 Conclusion

A nurse-led NAC tattooing clinic represents a feasible and complex intervention within the context of breast cancer care. The treatments administered exhibited high levels of tolerability, personalization, and quality of cosmetic outcomes. Although subject to the influence of available resources, its sustainability—considering continuity and completeness—appears promising. The use of accountability instruments and competence development serves as protective factors. The implementation of this service has empowered a support network by engaging both community members and healthcare professionals in collaborative efforts, thereby providing a crucial final step in care that may significantly impact psychophysical recovery.

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Chapter V

The patients' perspective

5.1 Introduction

The qualitative findings related to Endpoint 4 will be presented in this chapter. It is important to note that meaningful viewpoints also emerge from qualitative findings. The impact of scars on patients' satisfaction with their appearance, as well as the role of past treatments as a reminder of these marks, has been well documented [1]. Notwithstanding, there is a paucity of qualitative insights into patients' experiences of NAC tattooing. A focus on health outcomes impacted by the intervention should provide integral information on its meanings and implications for practice.

5.2 Methods

To reach data saturation, up to 15 participants were considered for the interview, from the cohort of patients who undergone NAC tattooing during the period from January 2023 to August 2024 (N = 62). Patients that fulfilled the following criteria were included: (1) adult, (2) female, (3) being able to speak and write in Italian; (4) willingness to participate in the study and sign written informed consent; (5) have undergone oncological breast surgery with removal of the NAC; (6) have received and completed NAC tattooing treatment. Whenever possible, we prioritized patients treated after the first trimester, so that the data collected were relative to the full organizational capacity of the outpatient clinic.

Ethical considerations

The authors acknowledge and emphasize the importance of ethical principles throughout the research process, reflecting on the complexities of adhering to these principles and supporting the decisions made during the study [2]. The study protocol was approved by the Area Vasta Emilia Nord ethic committee as described in the previous chapter.

Rigour and Fidelity

Rigour is essential to ensure the credibility, dependability, and transferability of findings that inform patient care and clinical practice. Methodological rigor and fidelity to the data were pursued through various strategies. Individual interviews were audio-recorded, transcribed verbatim and immediately deleted after transcription, with the consent of the participants. I conducted the interviews, through an

interview's guide (Appendix B). The thematic analysis was conducted according to the planned methods: the research team involved was composed by nurses with research training and they were all familiar with qualitative analysis and cancer care. The COREQ criteria for reporting qualitative research have been followed [3]. Reflexivity was considered, by engaging in ongoing researchers' self-reflection, acknowledging their influence on data collection and interpretation [4].

Data collection

I contacted patients by phone proposing study participation. They were also informed about the option to bring a photo (on digital support or printed) at the interview meeting, which evoked meanings, emotions, and personal experiences related to the NAC tattooing experience. The "photo-elicitation" may facilitate participants in communicating their experiences, feelings and emotions, which can be difficult to recount [5]. This strategy has been recently applied in similar studies [6, 7], serving as a framework for discussion during interviews. The interested patients and the researcher agreed on a date for the meeting at the Research, EBP and IRCCS Unit. In that occasion, the study was described in detail, and then the patients willing to participate that met the inclusion criteria were included by signing a consent form.

Data analysis

Data were analyzed using an inductive thematic analysis according to the approach of Braun and Clarke [8]. Three independent researchers read and familiarized themselves with the interviews, generating initial codes. In a second phase, the codes were shared and discussed until an agreement was reached, after which the research team defined the codes and began generating initial themes. Using the constant comparison method, sub-themes and themes were identified. All analyses were performed in Italian, and the results were translated into English. The data were analyzed manually and managed using Excel for Windows.

5.3 Findings

Ten women were included in the study. According to the study's objective, interviews' analysis allowed us to identify several themes that emerged from participants' NAC tattooing experience. We examined three marco-themes: "Patient perspectives on nurse tattooists"; "Patient perspectives on the organizational aspects"; "The effects of NAC tattooing on health". Detailed information on the related themes and sub-themes is summarized in Table 1 and Table 2 and further described through the paragraph. Some

contextual factors' explanation that we considered important to present concludes the section.

Macro-themes	Themes	Exemplifying quotations
Patient Perspectives on Nurse Tattooists	Nurses' attitudes	<i>"Very well, they are exceptional, very skilled, very kind, very sweet. I really can't say anything because I felt very good." (P2)</i>
	High professional and relational competence	<i>"No, no, they were good, I didn't expect anything different, the work is beautiful, they are very professional, I liked it, they did a good job in terms of skills, and if we talk about their way of doing things, they are spectacular." (P1)</i>
	Personalisation of the intervention	<i>"(...) the idea that not only are they there and they know what they are doing with their experience, let's put it that way, but they also know who you are i.e. you are coming and they also have an idea of who they have in front of them". (P9)</i>
	The nurses' passion for a "chosen job" make the difference	<i>"So really very, very positive impact, a group that you could tell had also chosen to do this thing, it wasn't something imposed... I think it makes a bit of a difference because maybe they could put into practice their propensity, perhaps even artistic because I don't think everyone can have the hand to do this." (P6).</i>
Patient perspectives on the organizational aspects	Equally accessible NAC tattoo clinic that completes a care pathway	<i>"Then, I think it's a big deal in the sense that if one had to pay €500 to do it privately... here they give this opportunity, I would have even paid something because it's a thing they do with - now I don't quite understand with some voluntary things - and so I think it's a fortune." (P1)</i>
	Structured and dedicated service in a hospital environment creates trust	<i>"The fact that it is inside a facility that deals with the issue comprehensively and is also specialised in that area, so... it's true that it's a tattoo on an area that has been operated on, on scars, so it's a bit unusual, and the skin is also a bit unusual, and it certainly gives you much more confidence than going to a tattoo artist who may be very good but who is used to drawing motorcycles, I mean, it's not the same thing, I think it's a bit different..." (P9)</i>
	Continuation of service is essential	<i>"I really hope it's something that will be carried forward because I absolutely agree that it's fundamental, and it's managed by professionals who are also humanly golden, which is not always taken for granted, so I really hope this project has a long life." (P8).</i>

Innovative clinic and distinctive personalisation of care

"(...) I saw the added value of almost a one-to-one relationship, I don't know, even this way you contact me to make an appointment, it's like someone is taking care of me and not vice versa, that is, I have to look for people to make appointments, go through the cup, I don't know, even this aspect of remembering you." (P6).

Table 1 - Patients' perspective on professional and organizational aspects.

Macro-theme	Themes	Sub-themes	Exemplifying quotations
The effects of NAC tattooing on health	Relationship with self-body image.	Cosmetic outcome satisfaction	<i>"Well, yes, extremely satisfied. In the human body, differences exist regardless, so breasts are no longer identical, but they probably weren't even before. So, no, satisfied. It's not like I was asking for the moon, far from it. No, no, very satisfied." (P10).</i>
		Selfcare	<i>"You know, taking a shower... my husband has always seen me as robust, and I am robust, but then also all cut up, this is no longer there... and then, you know, if one... I believe even at ninety years old, if one cares about the person, I don't say oh, but I say modestly; however, it is something that helps... it helped me a lot." (P4).</i>
		Psychological wellbeing	<i>"(...) but also from a psychological point of view because the way you look at yourself is more normal, less mutilated if I can use the right term compared to before." (P6).</i>
		Retrieved femininity	<i>"There's nothing to be done after, there's no age that matters, because you can be young, you can be quite advanced, but these are things that are very important for a woman." (P2).</i>
	Recognising yourself	Feeling complete again at the mirror	<i>"(...) but it is your inner eye that makes the difference much more than the eye of another, so the fact of seeing yourself again in a symmetry and organicity of the body made a huge difference. I chose not to reconstruct the nipple, only to tattoo the areola because I didn't want further complications... However, the areola gives you your integrity, it gives you a complete vision of yourself, and I repeat, it remains perhaps more for you than for others. This is at least my feeling." (P6).</i>

	Feeling normal again at the mirror	<i>"(...) unfortunately, the path I took, and every time I looked in the mirror, I didn't like myself even though they did a good reconstruction, but you see that it's different, and this makes you feel a bit more similar, that the two breasts are more alike because for a woman, I think it's really - surely it will be the same for a man - but for a woman, every time you wash, you dress, you see yourself in the mirror, with that... let's say it gives you a bit more self-confidence." (P7).</i>
	Going beyond sickness and loss	<i>"Because psychologically, the reconstruction and therefore also the nipple tattoo really made a difference because it brings back a normality that you had lost for more than a year because between one thing and another, it takes that time. Instead, I saw that psychologically it really turned things around because from then on, I started thinking much less about the disease and seeing myself more as a healthy person, a woman: you really rebuilt yourself, you put the pieces of the puzzle together, you became a woman again." (P9).</i>
Social relationships	Facilitating the intimacy with the partner	<i>"(...) it also helps in private life." (P8).</i>
	Facilitating social participation	<i>"Yes, more a sense of security, it's also true yes yes maybe you notice it less also because of that because you are a bit more relaxed yes yes it's true" (P8).</i>

Table 2 - NAC tattooing's impact on health and daily lives.

5.3.1 Patient Perspectives on Nurse Tattoos

Women's perspectives on nurse tattooists emphasized themes related to skillfulness and interpersonal attributes: "Nurses' attitudes," "High professional and relational competence," "Personalisation of the intervention," and "The nurses' passion for a "chosen job" make the difference". Women frequently remarked on the nurse tattooists' kindness and availability beyond their technical proficiency: *"(...) they are an embodied smile"* (P1). This attribute further contributed to the perception of a team that is sunny and inclusive. Moreover, the recognition of nurses as "humanly golden professionals" highlights the profound impact of their compassionate and empathetic approach. Additionally, patients consistently

highlighted the exceptional skillfulness of the nurse tattooists, expressing high satisfaction with the technical execution of the procedures. The integration of technical expertise with effective interpersonal communication was frequently described as high professional and relational competence, which is the second theme. Patients consistently reported increased confidence because of the nurses' expertise, their "safe hands" (P4): this reflects the reassurance that patients felt when they knew that the nurses had received specialized training in tattoo procedures, particularly for medical applications:

"It certainly gives you more confidence, the fact that they studied how to do tattoos, especially that type of tattoo, so yes, that gives much more confidence." (P9).

The provision of proper information, which generates tranquility, was identified as a critical factor in patient comfort and trust. Nurses' ability to effectively communicate and alleviate anxieties was highly valued. This aspect is linked with the third theme, "Personalization of intervention." Patients appreciated the nurses' attention to detail and their ability to tailor the procedure to individual needs and preferences:

*"(...) then I don't know, I'm still thinking about the color, right? 'Put a drop because then it becomes a bit darker, better a bit lighter'... but who has this attention? (...)
(P4).*

The effort to achieve desired aesthetic outcomes emerged. The understanding that nurses "know who you are" further solidified the positive perception of personalized care. Finally, the passion of the nurses for their chosen job was perceived: patients recognized that nurses were intrinsically motivated, which led to a superior experience:

"(...) and above all, I saw a lot of passion in what they were doing, I didn't perceive it as just another job to do but as almost a choice, so very passionate, very precise in wanting to achieve an excellent result, even much more than I would have requested (...)" (P6).

This intrinsic motivation, often associated with an "artistic propensity", was seen as directly influencing the quality of care.

5.3.2 Patient Perspectives on the Organizational Aspects

Participants expressed their viewpoints on the organizational structure and functional aspects of a NAC tattooing clinic. The following themes arose: "Equally accessible NAC

tattoo clinic that completes a care pathway”, “Structured and dedicated service in a hospital environment creates trust”, “Continuation of service is essential”, and “Innovative clinic and distinctive personalisation of care”. Women frequently emphasized the significance of equitable access to the clinic, particularly highlighting its accessibility compared to private alternatives:

"Well, it was a delightful surprise because I don't know how this service came about, but I repeat, it's a big deal because even just doing it privately, I don't think everyone can afford it..." (P10).

The therapeutic role of the tattoo was described as a necessary completion of the reconstruction in the breast cancer care pathway:

"(...) once the nipple is reconstructed, yes, but there was still something missing, it wasn't the same thing, and instead seeing the tattoo there, yes, and indeed I was surprised because really the first impact was really not reconstructed, not tattooed, so it's really the completion that is absolutely needed, without it something would be missing, it really makes a difference." (P8).

The second theme reveals that the presence of a dedicated, complete, and specialized service within the hospital enhanced trust. Patients felt secure knowing that experts were overseeing their care: women strongly advocated for the continuation of the service. The appeal to encourage the service because *"It's Worth It"* (P3) was explicit. In conclusion, the perception of an innovative and distinctive service contributed significantly to patient satisfaction and the overall positive experience. The concept of taking charge as an added value resonated strongly with patients, who appreciated the proactive and individualized approach to their care.

5.3.3 The effects of NAC Tattooing on health

This section presents the health outcomes impacted by NAC tattooing. It illustrates the themes dividing them into three themes: “Relationship with self-body image”, “Recognising yourself”, and “Social relationships”.

Relationship with Self-Body Image

“Cosmetic outcome satisfaction”, “Selfcare”, “Psychological wellbeing” and “Retrieved femininity” were the sub-themes related to body image issues. Cosmetic Outcome

Satisfaction indicated an excellent achievement of aesthetic results. The tattooing process also appeared to foster an increased engagement in Self-Care. Several participants described a renewed sense of comfort and acceptance of their bodies in daily routines, such as showering. NAC tattooing significantly contributed to patients' psychological wellbeing. Patients reported a shift towards a more normalized and less "mutilated" perception of their bodies:

"But psychologically it makes a difference: it makes a difference because even that evening where there were women who also expressed their opinion, and I agree in the sense that you say 'well, I see what changes'... but it changes a lot because if it's not there, you see this somewhat shapeless thing, you seem a bit mutilated. Done and done well, I immediately said, 'Ah, this one is more beautiful than mine,' then you look at it, you look at it with admiration. It's true that it's still something(...): making it as similar as possible, in my opinion, for a woman makes a difference, psychologically speaking, it makes a difference." (P1).

A critical outcome of NAC tattooing was the perceived retrieved femininity. Patients reported a restoration of their sense of womanhood, often describing a transformation from feeling incomplete to feeling whole again. The importance of this aspect transcended age. One patient powerfully stated:

"I'm not saying I'm like before, but yes, now I'm a woman, before... not a monster, but... but you could see the difference." (P2).

Recognizing yourself

This area focuses on how NAC tattooing aids in self-recognition, restores a sense of normality and helps individuals transcend the pervasive impact of illness. The themes are: "Feeling Complete Again at the Mirror"; "Feeling Normal Again at the Mirror", and "Going beyond Illness and loss". Women often describe the sense of completeness as an internal experience, a personal perception of body integrity that transcends external validation, as *"(...) it is your inner eye that makes the difference much more than the eye of another (...)" (P6).*

NAC tattooing substantially contributes to patients' feeling normal again at the mirror, increasing self-confidence. Participants described shifting from avoiding self-reflection to actively engaging with their image, perceiving themselves as "normal.":

"I always tried to... shower... t-shirt... bra... and let's not talk about it. Now I even go out with a towel... because you feel different, it helps you to be... how can I say... more normal to others... and it's not... how can I tell you... it's not easy because when certain things happen to you, you no longer feel the same as others for what I told you before. Now, instead, I feel more normal, more like others, even with my husband, for example, because you know..." (P4).

Going Beyond Illness and Loss

NAC tattooing plays a pivotal role in enabling patients to go beyond sickness and loss, shifting their focus toward a picture of health. The intervention acts as a psychological buffer against constant reminders of past medical interventions. One participant described the daily ritual of showering:

"Every time you take a shower, you look in the mirror, everything comes to mind, everything comes to mind: now it comes to mind less, it comes to mind less, because looking at myself..., because you know, sometimes you remove... now I take a shower... and it lifts your spirits, you feel more at ease with yourself because you are more normal." (P4).

The tattoo is perceived as a "drip of life" that facilitates a positive emotional shift:

"And so, when you go there (the clinic), when you go home... it's a drip of life: not just the tattoo, then the tattoo helps you every day that... for example, in the evening you take a shower (...), it makes you smile, (...) and so they are all touches of life... it's like when you go for exams, and they tell you the tumor is not there... it's not there, good! It's a touch of life, and equally, when you take a shower, it's a touch of life!" (P4).

The cosmetic outcome of the tattoo helps to minimize the visual reminders of illness, as *"the eye always falls there..." (P10).*

Social Relationships

This area presents how NAC tattooing influences social interactions and intimate relationships. Starting with the first theme, "Facilitating Intimacy with the Partner", participants noted the impact on their relationships, suggesting that the tattoo helps remove

perceived barriers to intimacy. One patient reflected on the potential challenges in new relationships:

"(...) So it also influences that... I don't know, probably those who don't have... I mean, if I had to think about finding someone now because I was single, it would be a limitation, a big limitation." (P1).

Accordingly, the intervention facilitates social participation (second theme) by enhancing patients' comfort and confidence in social settings. Patients reported feeling more at ease in situations where their bodies might be exposed, such as gyms or swimming pools. One participant shared:

"(...) I also showed the tattoo to two ladies at the gym, because we were all women who had undergone surgery, last year I showed it to them, something I hadn't done before..." (P3).

The tattoo made patients feel *"presentable again"* (P6). This newfound comfort extended to practical daily situations:

"well, it certainly gives you more freedom because actually thinking about changing in a locker room and not having the nipple made me very uncomfortable (...)" (P8).

"Yes, without a doubt, I go to the pool and I rarely took a shower in the locker room because I didn't like having people's eyes on me or maybe the look a bit like that... now it's much more, everything is more normal, that's for sure." (P10).

5.3.4 Contextual factors

Definitions and meanings of the overall experience have also emerged in relation to the personal context. NAC tattooing was considered a therapeutic possibility not available years ago, with significant advancement in care. One patient drew a stark contrast with past medical practices:

"(...) it was 1973, so the operations were devastating, there was no chemotherapy, there was cobalt therapy, so there were all these things... I went through all these stages, it's what my mother couldn't do, she died very young anyway... and so I... I did these things for her too, because she must have gone through some tough times... I went through difficult times, but she even more so." (P2).

The experience was consistently framed in favorable terms like "*A Beautiful Experience*" (P2), "*A Positive Thing*": (P3), "*A Nice Afternoon*": (P4), "*A Good Opportunity*" and "*A Pleasant Surprise*": (P9), "*A Ray of Light*". This last quote has been deepened in its meaning, with contents express by a participant through the photo-elicitation (Figure 1):

"(...) then suddenly I understood that I had to do this thing too, I mean, for me it was... I mean, now I'm even fond of it, I can't wait to come for touch-ups, I can't wait... because I see myself better... so I always say that when something beautiful comes to me, it comes from heaven (...) Now I find a ray of light, I find it and every beautiful thing that happens to me, I say yes." (P4).

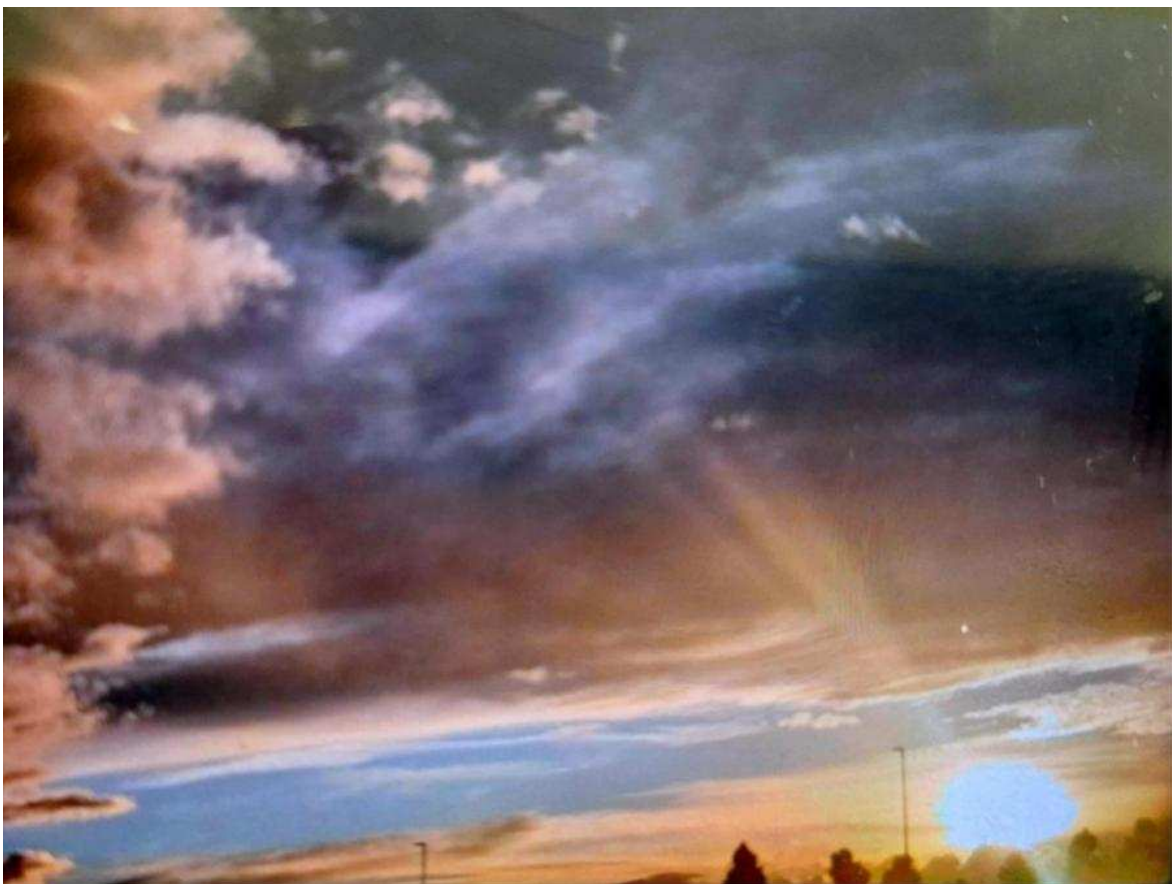


Figure 1 - Ray of light on dark clouds.

Women frequently expressed profound relief after years of long and complex treatments, viewing the NAC tattoo as a conclusive and positive step in their arduous journey. One participant highlighted the extended timeline of their reconstructive process:

"(...) also because I already had a long journey for reconstruction before putting in the prosthesis because of COVID, the times were greatly extended, and because I

had the mastectomy in 2018, so it was a long process before the expander, and then the times were extended to be able to put in the prosthesis, so that was already a bit psychologically heavy, and so this nipple thing is very positive for me, fortunately, it's there." (P7).

Participants noted other contextual factors that we considered relevant for a comprehensive understanding of their experience. Data regarding the initial steps of the NAC tattooing consideration emerged frequently. Some factors initially acted as barriers to patients deciding to get the NAC tattoo: the high cost of treatment at private clinics, the aesthetic result not directly visible to others, and the advanced age. On the other hand, the fact that the clinic was covered by the National Health Service encouraged participants. In addition, several facilitators collectively highlight the importance of clear communication and peer support: the sharing of information with those who have already had the tattoo, the involvement of the plastic surgeon in the decision making, and the simple management of the tattoo.

Complex but Complete Care: Not Just "Surviving"

Women recognized the value of complex but complete care, extending beyond mere "surviving". This signified an acknowledgement of quality-of-life aspects' relevance:

"It's a continuous work because, well, if something goes wrong, I'm still on the list for another adjustment, so it's a long journey, but they follow you and really take care of you, they don't just do the necessary: you have the tumor to remove, let's remove it (...), but they still manage to follow you even in the 'less important' things: less important because you no longer risk your life, but those who have gone through it know, they are still important for a psychological reason, especially when you are of a certain age." (P1).

The concept expresses moving beyond just survival to focus on aesthetic and psychological well-being.

Dealing with a "Present Absence"

The profound impact of the absence of the NAC was consistently described as apparent and alienating. This absence often led to feelings of dehumanization. In particular:

- feeling almost like an “automa”: *"(...) the absence of the tattoo makes you feel almost like an automaton in the sense that it's a part that is no longer very human, it seems like a prosthesis, it gives you more the idea of a prosthesis." (P6);*
- feeling discomfort: *"(...) you know, when you have these operations, you feel the prosthesis, of course, you feel something different, then you take a shower, you see yourself even more different because of the cuts here and there, the prosthesis that goes here and there... you feel a foreign object inside you..." (P4);*
- not feeling like others: *"(...) it's not easy because when certain things happen to you, you no longer feel the same as others." (P4),*
- because “the eye falls there”: *"Yes, the eye falls there... because it's something different from usual, like a mole...it's like something that, due to its absence, not its presence, attracts attention." (P10).*

The importance of sharing and the support of the family and the professionals

This overarching theme emerged as crucial for patients navigating their journey:

- sharing: *"(...) I have my colleagues, all women, and they always asked me, they asked me sometimes, I mean, they even asked me if I would show them my breast, yes, because of curiosity, because of fear, because unfortunately now almost all families have tumors, and so this comes up. They being women, this fear comes up that maybe one day it might happen to them too." (P7);*
- understanding the importance of the reconstructive phase: *"For me, the first thing was to take care of myself and get out of this moment as quickly as possible, but it was essential that someone was committed to helping me understand that this aesthetic and reconstructive phase would also be important because it was, I mean, if for some reason I had said I don't even want the expander, the important thing is that you treat me, today I would be very sorry because then you can't go back on certain decisions, but even the effort of the expansions, the umpteenth reconstruction, so another surgical operation, despite their efforts, today has given me back an important image of myself." (P6);*
- family support: *"I had a family that helped me with this because maybe there are also situations where it is more pointed out, I was helped in this journey." (P5).*

5.4 Discussion

The qualitative study aimed to comprehensively explore the perspectives of women treated with NAC tattooing. The methodology employed in this study enabled a thorough analysis of the participants' experiences, ensuring the validity of the results. The findings on the health impact contribute significantly to filling the research gaps in the field, as several key themes indicate that NAC tattooing is a multifaceted intervention with profound implications for psychosocial wellbeing, body image, and the overall recovery trajectory. Furthermore, from an organizational perspective, the interviews yielded invaluable insights for clinical practice and the continuous evaluation and refinement of the project. In line with the literature [9], the intervention is regarded not as a superficial cosmetic enhancement, but rather as a crucial and therapeutic conclusion to the breast cancer care pathway.

Findings reveal that the participants identified two key strengths of the service: its accessibility and its validity. The financial benefits of a free service have been shown to increase its accessibility, as well as facilitating contact with nurses during the appointment stage and after each treatment. This is related to the sense of trust with the team: participants stated a clear preference for specialized medical environments over general tattoo studios for these specific procedures. In the context of future research, it is recommended that a patient-point-of-view on organizational aspects be given greater emphasis. This approach has the potential to integrate the perspectives of professionals, thereby offering a more comprehensive representation of NAC tattooing contexts, along with their respective advantages and disadvantages. Participants consistently emphasized a synergy between high professional skill and strong interpersonal attributes, such as empathy, kindness, and a perceived passion for their work. This holistic, patient-centered approach is reassuring, as the personalization of the intervention is intrinsically tailored to individual aesthetic preferences, medical conditions, and emotional needs. This was perceived by participants as a positive aspect of the care provided, with the attention to detail, enhancing their satisfaction and creating a sense of being known and cared for. A service that provides apparent accuracy and familiarity has the potential to reinforce the credibility of the overall pathway. Participants viewed the hospital-based clinic as a structured, trustworthy, and accessible service that legitimately "completes" the surgical reconstruction process. The accessibility of this service within the public healthcare system, as opposed to private alternatives, was identified as a key factor for equitable care.

The most significant outcomes reported were the profound effects of NAC tattooing on psychosocial wellbeing. The intervention was consistently associated with the restoration of

positive body image. It is noteworthy that the daily satisfactory self-perception with the new NAC improved self-care, thereby renewing a sense of femininity. In the context of discourse about body acceptance and emotional recovery, participants frequently alluded to intimate moments, such as mirroring or showering, as being imbued with significance. As stated in quotes in paragraph 5.3.3, lingering in a "new" reflection engendered a feeling of confidence. Participants described a transition in their perception of their bodies, moving from a state of self-perception as "mutilated" or "incomplete" to a sense of normality. This normalization was a crucial factor in facilitating self-recognition and reducing the daily visual reminders of illness and loss. As introduced, visual reminders represent a challenging issue for breast cancer patients [1]: NAC tattoo is an example of a supportive intervention addressing this point. The tattoo is theorized to have functioned as a symbolic endpoint, facilitating a cognitive and emotional shift toward a renewed sense of self as a healthy and whole person. Consequently, social functioning was enhanced, as evidenced by increased confidence and ease in social environments such as gyms and swimming pools, along with a reduction in barriers to intimacy with partners.

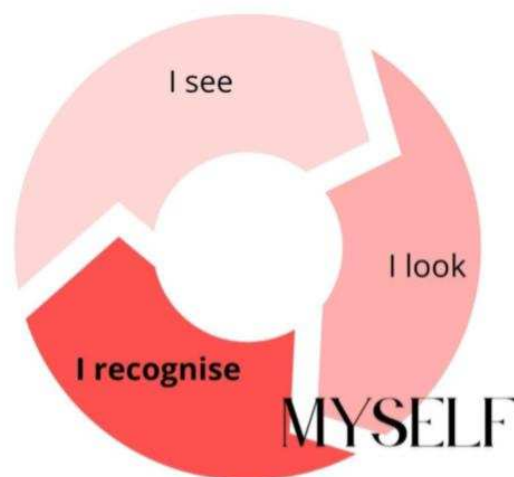


Figure 2 - Self-perception aspects implicated in NAC tattooing.

The mechanisms presented in the model in Figure 2 are interconnected, as evidenced by the correlation between NAC tattooing and multiple levels of awareness through body image perception. This ranges from the simple act of seeing oneself in the mirror to the consistent observation of oneself as a woman. Through this reflection, women can gain a new perspective on themselves, which fosters a sense of normality, confidence, and a healthy

self. The positive role in coping is noteworthy, as participants clearly highlighted it. The concept of 'multilevel awareness' refers to the various levels of consciousness and understanding that individuals develop about their bodies and themselves through the NAC tattooing process. The past, characterized by the prevalence of illness and protracted treatment regimens, is perceived as bearing a diminished weight and intruding less profoundly. This is a subject worthy of further study, as is the relationship between social participation and the outcomes mentioned. Multilevel awareness is presented as a circular process, whereby behaviors connected to the self, partners, and others reinforce each other in a chain that ultimately enhances the quality of self-care.

Both organizational and health-related aspects were further elaborated with context considerations, often highlighting contrasts. For instance, the local oncological approach was highly valued for its comprehensive and holistic nature. The profound psychological impact of the absence of the nipple was a recurring theme in the interviews, underscoring the transformative function of the tattoo, metaphorically represented as "drips of life", in alleviating these sentiments. The diagnosis and subsequent treatments had been a period of considerable darkness, but the patient was now able to see the light at the end of the tunnel. The "ray of light" that appears in the photo-elicitation of one participant helps visualize the intensity of this impact. It is noteworthy that the experience is intrinsically linked to both familiar historical contexts and the innovative possibilities in care that scientific advances have rendered possible. Furthermore, interviews frequently emphasize the multifaceted support systems integrated into the care pathway, including the opportunity to share perspectives, doubts, and personal experiences with other patients. These contextual features were found to be instrumental in reinforcing the comprehension of the findings.

While the present study provides valuable, in-depth insights, the small sample size (N = 10) could have limited a comprehensive understanding of the phenomenon studied. This study forms part of a larger feasibility study of the ARCADE nurse-led clinic. It is recommended that future research employs both mixed-methods approaches and larger qualitative studies with a focus on the observed health benefits. Moreover, only one participant chose to begin the interview with the photo-elicitation: a greater adherence would have enriched the contents of the study.

5. Conclusion

This study provides compelling evidence that nurse-led NAC tattooing is a high-impact therapeutic intervention. The ARCADE nurse-led clinic has been shown to fill a crucial gap in patient care and is perceived as valid, safe, and equally accessible. NAC tattooing represents a critical component of psychosocial recovery for breast cancer survivors, contributing to the restoration of body integrity and personal identity. Whilst further studies are required to establish the reliability of these correlations, preliminary findings suggest that the positive effect on body image perception may facilitate social functioning and psychological recovery from the impact of disease and medical treatment.

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Discussion

1. Synthesis of main results

The project has achieved its stated objective: namely, to describe how can a nurse-led NAC tattooing service, for patients who have undergone breast cancer surgery in the setting of Azienda USL-IRCCS of Reggio Emilia, be developed and adapted to the local healthcare context, also assessing its feasibility and the impact on patients, professionals, and the organization.

As outlined in Chapter I, the application of NAC tattooing within an oncological context is an example of a complex intervention in healthcare. Complex interventions consist of multiple interacting components and are frequently implemented within service delivery contexts across diverse fields. To accomplish the overarching objective outlined above, the MRC framework for the development and implementation of complex healthcare interventions was followed. The first development phase was included in WP1, while WP2 comprised the feasibility and evaluation phases. Preliminary results have been presented, and it is therefore proposed that the implementation should be assessed in further studies.

Chapters II and III described the content of WP1. A literature review was conducted to identify and synthesize the literature focused on medical tattooing for NAC reconstruction in women who underwent breast reconstruction following breast cancer surgery. Notwithstanding the methodological deficiencies, research on NAC tattooing is pertinent as it facilitates women in the process of redefining their identity following debilitating cancer treatments. The principal findings indicate a necessity for additional research to be conducted on processes and outcomes. The overall quality of the literature, which consisted in eleven observational studies and two pilot experimental studies, was deemed to be inadequate. The professionals primarily implicated in the NAC tattooing reported by these studies were nurses. The professional training is inadequately delineated in six papers. The implementation of nurse-led services was also described, and the most frequently assessed outcome was the satisfaction rate.

Pursuant to the findings of the literature review (Step A) and the context analysis (Step B), an initial intervention was scheduled (Step C). As outlined in Chapter III, the NAC tattooing service underwent significant developments, encompassing Steps B and C. This process involved the active involvement of the Breast Unit and the Research Department, leading to the selection of three trained nurse-tattooists. Furthermore, the creation of informative material was initiated, which was disseminated to

patients, families, and local associations, fostering active engagement and participation in defining the clinic's official name. The setting and materials were then defined. A monthly schedule of activities was established, with patients who met the criteria for NAC tattooing being contacted by the nurse case manager. Each treatment program consisted of three to four sessions, scheduled 30 to 40 days apart, and was conducted in an ambulatory setting. The procedure involved the use of NAC shaping and tattooing with a dermograph and sterile needles.

Chapters IV and V illustrated the content of WP2. To assess the feasibility of a nurse-led NAC tattooing clinic in the context, the ARCADE_M study was implemented. This was an observational mixed-method design. The ARCADE_M's objectives were: firstly, to assess the organizational sustainability of the nurse-led NAC tattooing clinic (Endpoint 1); secondly, to evaluate the cosmetic outcome of the NAC tattoo (Endpoint 2); thirdly, to explore the professionals' perceptions on their involvement in the NAC tattooing clinic (Endpoint 3); and finally, to explore the lived experiences of the tattooed women (Endpoint 4).

- The initial endpoint of the study consisted in a retrospective analysis of activity and process data from the ARCADE clinic. The results of Chapter IV demonstrate that the activity exhibited a standard character in terms of timing and materials. The 100% of the sample (N = 33) achieved a satisfactory cosmetic result, with no adverse events or other complications, such as excessive color fading or pain. In fact, 79% of cases experienced either none or only mild symptoms.
- The second endpoint of the study consisted in the analysis of the photographs of the tattooed NAC by a panel of experts. The photographs were analyzed according to objective criteria, including symmetry, coloring, and 3D effect. A total of 22 sets were retrospectively retrieved and analyzed. The tattooed NACs demonstrated excellent quality, achieving a medium score of 4.7 out of five for color similarity and symmetry, and 4.8 for 3D effect.
- The third endpoint of the study consisted in a qualitative investigation, in the form of semi-structured interviews, which involved five professionals (two nurses, one surgeon, and two managers). The primary macro-themes encompassed considerations pertaining to the value of the clinic, the barriers and facilitators encountered, and the associated future requirements.
- The fourth endpoint of the study consisted in a qualitative investigation, in the form of semi-structured interviews, which involved patients. Participants (N = 10) identified two key strengths of the service: its accessibility and its validity. Furthermore, a correlation between

NAC tattooing and multiple levels of awareness through body image perception was evidenced: it enabled women to attain a novel perspective on their identity, fostering a sense of normality, confidence, and a healthy self-image. A positive role in coping was also highlighted: the past, characterized by the prevalence of illness and protracted treatment regimens, is perceived as bearing a diminished weight and intruding less profoundly.

Chapter IV concludes that the implementation of a nurse-led NAC tattooing clinic constitutes a feasible, complex intervention for the management of breast cancer. The integration of the retrieved data analysis and the data generated by the qualitative approach underscores the pivotal role of resource availability and personnel motivation in determining goal achievement, as well as the promotion of accountability and the development of competence. The implementation of this service resulted in the establishment of a support network, whereby the community and professionals engaged in collaborative efforts to provide this final step of care, which can be crucial for psychophysical recovery.

Finally, Chapter V concludes that nurse-administered NAC tattooing constitutes a high-impact therapeutic intervention. The ARCADE nurse-led clinic has been demonstrated to address a significant gap in patient care and is regarded as reliable, safe, and equally accessible. NAC tattooing is a critical component of psychosocial recovery for breast cancer survivors, contributing to the restoration of body integrity and personal identity. Further studies are required to establish the reliability of these correlations. However, preliminary findings suggest that the positive effect on body image perception may facilitate social functioning and psychological recovery from the impact of disease and medical treatment.

2. Steps towards the implementation

The final procedure has been completed (Appendix C). The complex intervention methodology enabled the identification of various actionable areas and both positive and negative aspects of healthcare services, as demonstrated by similar studies in the field of breast cancer [1, 2]. This project confirms that a multi-stakeholder, mixed-methods research approach is appropriate for addressing complexities and gaps in evidence [3]. Considering these results and the necessity of up-to-date evidence for an accurate intervention refinement, a narrative synthesis was conducted to summarize the latest evidence on NAC tattooing. The amount of literature from 2023 to February 2025 on the topic has increased, along with the technique application and its research interest. It addressed current research gaps, like quality-of-life assessment with validated instruments and organizational aspects. In line with previous literature, NAC reconstruction's relevance, satisfaction with the cosmetic outcome,

the fading phenomenon, and the factors influencing color durability were other outcomes assessed. Emotional, psychological, and sexual domains are patient-reported outcomes that benefit from NAC tattooing. Sustainability and professional training remain critical issues worthy of further comprehensive studies. These results are in line with the findings presented, leading to the identification of seven intervention areas that represent the main challenges and future opportunities associated with ARCADE implementation:

1. Dedicated and motivated personnel.
2. Accountability promotion and data-driven model for quality assessment.
3. Formalize the service in the clinical pathway, enhancing team coordination.
4. Efficient management of the requests.
5. Competence, maintenance and evaluation.
6. Validation of specific training.
7. Concile long-term sustainability with high-level performances.

The integration and formalization of services, as well as the definition of the training pathway and resource requirements, were the main issues faced after this complex intervention evaluation. As Table 1 shows, the actions taken to overcome the detected barriers were building blocks that provided solidity and stability to the service, fundamental for its inclusion in the breast cancer pathway of the healthcare facility.

Challenge	Action	Description	Time frame
3	To share the strategy and the vision	The Research, EBP & IRCCS Unit and the health professions of the oncological department discussed these priority work areas described in Table X with the administrative director of the hospital facility and the health professions director of the integrated clinical care network. They also met with the nurse tattooists and the plastic surgery service director for further feedback on recent activities and plans. The vision was developed from a shared perspective of feasibility, sustainability, and training and focused on the significance and necessity of its inclusion in a precise care pathway. The added value that the public service can provide is its highly specialized and evidence-based care in a comprehensive cancer care framework.	Oct – Nov 2024

2,3	To guarantee safety, quality and continuity	The team refined the procedure, consent, and organizational documents necessary for the service formalization. The service is considered a nurse-led clinic within the hospital's plastic surgery unit.	Dec 2024 – May 2025
5,6,7	To define training, competence levels and indicators	<p>The team established an annual training plan for nursing competence in NAC tattooing of cancer patients. It aims to:</p> <ul style="list-style-type: none"> • provide and consolidate theoretical and technical knowledge on NAC medical tattooing. • develop competence in taking charge of the person candidate for NAC tattooing. • Promote professionals' autonomy in performing the NAC tattooing procedure. <p>Blended modality training, incorporating both theoretical and practical frameworks, is conducted within an extendible 30-hour plan. Initially, practice will be conducted on available clinic days with minimal impact on activities.</p>	Jan – May 2025
1,7	Better staff management to provide continuity and sustainability	Personnel stabilization at the clinic encountered several barriers due to their transfer from other working settings, even within the territory. In the first months, services coordinators of the nurse tattooists were contacted to ensure their collaboration in facilitating shifts and transfers between hospitals. An agreement has been reached, dedicating the more expert nurse to the clinic three working days a month.	Jan – May 2025
2,3,4	To guarantee safety, quality and continuity	<p>To provide materials supply, a 2-year contract for needles and pigments has been settled with the provider.</p> <p>The patient pathway begins with the medical indication for tattooing. Medical staff will also evaluate and order consultations with specialists, such as dermatologists or allergists. Then, a computerized request is forwarded by the surgeon through the internal hospital system, allowing the patient to schedule the first appointment. That medical request has a coded referral for NAC tattooing care (86.02.3), which is reimbursed by the NHS and included in the essential levels of care in Italy. The agenda at this point is editable by the breast unit case manager with appointments and notes.</p>	Feb – May 2025
2	To systematically collect complete clinical information.	The team collaborated with the informatics department of the healthcare facility to develop an electronic chart integrated with the hospital's Electronic Health Record System. It tracks patients' anamnesis, medical indications, NAC projects, operational data for each session, and follow-ups. Photographic devices are connected to the system for a secure and systematic collection of photos before and after the sessions.	Feb – May 2025
3,7	To renew the dialogue and engagement with patients, associations,	As in the development phase, the breast cancer patients' association was crucial in sustaining the project: two training demographers and synthetic skin for tattoo	Feb – May 2025

caregivers, and the community.	practice were donated. The team actively participated in community-open events, where the associations involved were invited to provide feedback on the project's evolution. Moreover, brochures for ARCADE were updated and refined to provide clearer information.
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Table 1 - Actionable barriers and challenges in ARCADE implementation.

Strengths and limitations

Empowering people with training makes it possible to increase activities safely, manage waiting lists effectively, and distribute the workload more efficiently. Moreover, the electronic agenda for appointments marks the beginning of formal activities and the regional information flow. Nevertheless, these preliminary data were not sufficient to complete an exhaustive cost evaluation. The cost of materials is around 50 euros for 3 tattoo sessions; the regional reimbursement is 16.80 euros for each session. Once space, time and human resources will be defined and implemented, it will be possible to proceed with cost-effectiveness evaluations and others that consider the health benefits for patients. Notably, the tattoo-only technique can be used with patients who refuse another operation for NAC reconstruction, as well as with those who have potential risk factors for a poor outcome following surgical NAC reconstruction [4]. In addition, cost savings are suggested, but these still need to be examined in detail [5]. The organisational aspects of similar implementations are often poorly documented in the literature and lack cohesion in an international context [6]. This makes this research useful and relevant but also makes it poorly comparable with similar studies. The small sample size considered for the retrospective analysis of data is another limitation to consider due to the ongoing development of the intervention structure, data were not always available or were incomplete. For the same reason, cosmetic outcome evaluations need to be improved, and the new integrated electronic chart will be crucial to overcome these problems. Moreover, similar supportive interventions after breast cancer surgery should also consider the male population, as supported by recent literature [7]. On the other hand, patients' associations strengthened the whole research project, from the development to the results' analysis: it permitted to continuously compare evaluations and actions to contextual appropriateness and receptivity. Community involvement is considered an integral part of the co-designed approach in oncology [8], and will be important in the next implementation phases.

3. Implications for practice

The significance of the clinic extends beyond the execution of the tattoo, as it plays a crucial role in breast cancer survivorship, completing the care pathway. It is envisaged that the capacities of this service can be extended sustainably, providing space, for example, for research, therapeutic education,

survivorship care, and referral to local services. In this comprehensive vision the nurse is a central figure, like this quote remarks: *“The nurse can really provide a response that goes beyond just the tattoo, but also in terms of support and guidance within our facilities, like the psychological support, if this need emerges during the reconstruction and tattooing process, and perhaps did not emerge in the previous stages of the journey”* (P1). Future steps will be necessary, starting with professionals’ training and a more comprehensive cost evaluation. Notably, professional and organizational aspects have been identified as complex and worthy of further focus [9]. Despite the development of encouraging training curricula [10], the need for greater consistency has emerged, including the exploration of the relationship between competence and patient outcomes. Technical and artistic expertise should be combined with advanced oncological care competence. Finally, novel and comprehensive approaches to research may help to continue the pathway of sustainability and personalization of care in this field, which are key factors for health intervention in complex healthcare systems.

Conclusions

The project demonstrated the potential of health service research in combining different outcomes and effects. In addition to the evaluation of effectiveness, this experience illustrated the methodology for the creation of a customised care model and its correlation with patient outcomes and professional value. A substantial body of research has demonstrated the efficacy of nurse-led care in enhancing patient-reported outcomes, including distress levels, quality of life, and depressive symptoms, among cancer patients [11]. Furthermore, remote care appears to be a promising model for delivering psychosocial interventions to breast cancer patients. It has also been demonstrated that the quality of life of cancer survivors is enhanced in specific domains, including cognitive and social functioning [12]. As demonstrated by Mahony et al., early contact with a specialist breast cancer nurse has been shown to have a positive impact on patients, health services and the healthcare system [13]. The organization of services has the capacity to influence these impacts and should be optimized according to the patient's needs and the local context. It is important to note that models have the potential to impact not only health but also financial expenditure. It has been demonstrated that early access to a breast cancer nurse results in annual net savings of \$6,323,257 (£4,884,323) or \$1,527 (£1,178) per new breast cancer patient [13]. Investment in cancer control has been demonstrated to have a positive impact on population health, in addition to delivering societal and economic benefits [14]. It is evident that the impact of breast cancer profoundly impacts the lives of women and the European economy. The psychological and physical repercussions of diagnosis and treatment can profoundly impact a woman's sense of identity, interpersonal relationships, and professional life. The economic consequences are equally severe, with the productivity loss associated with BC in Europe estimated at €7 billion [15]. Furthermore, it has been demonstrated that up to 53% of survivors do not return to their previous employment, resulting in substantial financial hardship for individuals and their families [16]. This underscores the broader societal implications of the disease.

The results presented in previous chapters underscore the necessity of integrating this service, as they suggest favorable effects on daily life, intimacy, and social participation. The ARCADE implementation within the public health service has the potential to facilitate the completion of the care pathway for breast cancer, thereby ensuring equitable access for patients. While technological and policy reforms are essential, there is a growing consensus that the active involvement of patients in all aspects of care, from design to evaluation, is not just beneficial, but fundamental to achieving equitable outcomes for all. Therefore, given the complex psychosocial effects of this cancer population, it is crucial to incorporate PPIE into care models. In the context of the ARCADE project, the active

participation of patients, families and associations proved to be of paramount significance. This involvement facilitated the aggregation of diverse perspectives, innovative concepts, and prospective trajectories during the project's developmental phase. Furthermore, the engagement of these constituents persisted throughout the project's duration, characterized by the organization of events that were designed to foster communal support. Following the conclusion of the mixed-method study, preliminary results were discussed during a nursing conference that was open to the community. The associations and the patients participated actively as an integrated part of the project.

However, as outlined in Chapter IV, the sustainability of the service must be monitored and pursued. Even considering that NAC tattooing can be performed as an alternative to NAC reconstruction, the outpatient nursing setting makes this a low-cost treatment option. It is probable that this alternative is more cost-effective than the utilization of a operating room with surgeons and anesthetists. Preliminary data has been collected, but it has not yet been possible to conduct an analysis of cost-effectiveness. This will be undertaken in future studies, once the service structures have been stabilized. A universal healthcare system is characterized by its firm roots in the principles of equality and equity, and a focus on responsible healthcare. These cornerstones provide the basis for the optimization of access to healthcare services, individual health outcomes, and the allocation of resources and services according to need, based on essential levels of care. The notion of welfare is intrinsically linked to that of value, encompassing skills, care, and responsibility. The specialist expertise of healthcare professionals plays a pivotal role in the relaunch of policies that enhance human capital. This is because it is an intrinsic incentive, a tool for accountability, and a guarantee of quality care for citizens [17]. In this intricate context, characterized by the prevalence of sustainability challenges, cancer is progressively assuming a chronic nature. There is an increasing necessity to provide support and enhance the quality of life for these patients during this sensitive period of adjustment to new habits, lifestyles, and energy levels. Treatment and diagnostic procedures become a substantial component of daily life, and the pervasive sense of uncertainty regarding the future can prove to be a formidable and stressful challenge, even for caregivers.

A NAC tattooing service may appear marginal at first. In fact, its impact on health outcomes can be significant. This is particularly true in relation to self-acceptance and coping. You can find more information on this in Chapter V. However, it should be noted that these findings are preliminary, and further studies are required to demonstrate strong correlations. In the event of the effects being confirmed, the ramifications for women's health will be manifold. In addition to the benefits, it is important to acknowledge that NAC tattooing has the potential to serve as an intervention that could enhance body image, which is a fundamental aspect of promoting health and wellbeing, and which is

widely recognized as a crucial element in the prevention of breast cancer. This could influence their approach to prevention, promoting rehabilitation and encouraging healthy behaviors, overcoming the fear of recurrence.

Maintaining services such as ARCADE demonstrates a clear value for competence, equity, and the right to health. As presented in Chapter V, the service, through the efforts of its healthcare professionals, has been able to convey an image of care that conveys a sense of familiarity and personalized attention. It expresses “I know you, I care”. Given the current challenges that the NHS must face, this reflection could help rebuild trust in the public system. It demands that we perceive healthcare expenditure not as a drain on national resources, but as a strategic investment in human capital, social equity, and economic stability. The adoption of data-driven innovation, the prioritization of prevention, and the restructuring of systems around value can facilitate the development of public healthcare systems that are not only financially sustainable but also capable of addressing the complex health needs of citizens over an extended period.

NAC tattooing is included in the essential level of care in Italy. However, it is imperative to acknowledge the necessity for more homogeneous implementations of similar services. The geographical location of an individual significantly influences their access to advanced diagnostic procedures, novel pharmaceuticals, and clinical experimentation, giving rise to a phenomenon of healthcare migration from southern to northern regions [18]. This places a considerable burden on patients and their families, whilst also demonstrating a systemic failure to guarantee the "inalienable rights" to care on a national level. In conclusion, the sustainability of cancer care represents the ultimate test for public health systems. This phenomenon compels a fundamental reassessment of our established priorities. True sustainability is defined by its active nature, with strategic investment in infrastructure, prevention, and innovation being integral components. This ensures that the significant progress achieved in the fight against cancer is accessible to all.

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Appendix A – Description of the intervention with the TIDieR (Template for Intervention Description and Replication) Checklist.

Brief Name	Why	What Materials	What Procedures	Who Provided	How	Where	When and How Much	Tailoring	Modifications	How Well
Nipple-Areola Complex Tattooing	When surgical treatment for breast cancer is indicated, body image issues can affect the quality of life, identity and relationships. The dermopigmentation is performed on people who need to cover pathological skin conditions, restore the appearance of healthy skin, or as an adjunct to reconstructive surgeries.	Local anesthetic cream; steril gauzes, towels, and gloves; bioresorbable pigments; dermograph and disposable steril needles. Information material like brochures, consent and anamnesis sheet; computer programs to manage list and appointments; camera.	In the first dermopigmentation session, the nipple-areola design is created (color, shape and overall appearance of the areola). During the minutes required for the anesthetic, the nurse conducts an individual interview to clarify all aspects of the procedure. The nurse will trace the material and any adverse effects during treatment. The nurses will leave an oily gauze on the spot to be removed about 3 hours later. At the end of the session, the patient will be asked to document the tattoo project with photographs from NAC. At home, patients should perform normal hygiene of the new areola with water and mild soap, without rubbing, but dabbing it. It is recommended to apply an emollient cream for 3 or 4 days, 1 or 2 times a day and as needed.	The breast surgeon recommends the treatment and supervises patients; the case manager nurse contacts women and manages waiting lists; the trained nurse tattooists perform tattoos and follow-up care. The research unit assesses and monitors the sessions, outcomes and other scientific and management aspects.	The appointment will be arranged by telephone, as also any follow-up contact. The sessions will be carried out in person.	Hospital Surgical Ambulatorial setting.	After six months from the last surgery, but still after the indication of the surgeon. A session can last 60 min for a single NAC, 90 min or more for bilateral dermopigmentation. Three sessions are scheduled at 30-40 days. One-year follow-up tattoo is planned.	Timing, personalization of shape and color, other technical aspects are considered. Patients have personal stories and different needs: the result will be customized and adapted to the characteristics and will of the patient. In some cases a fourth session is necessary.	Modifications may follow the monitoring initial results of the patient (feedback on satisfaction, adverse reactions, adhesion and cancellations), new requests and calendar of the agenda. It will be possible to modify the operating modalities of the treatments in order to face the necessary resources and costs (the continuous formation of professionals, materials, working hours and other events).	Adherence to treatment will be evaluated by keeping track of the procedure completed by each individual patient. Checklists on sessions will also be evaluated.

Appendix B – Interview guide

Preparation of the setting

When contacting participants, the purpose of the interview is explained, briefly introducing the research and guaranteeing anonymity. Upon request, or if this may help participants feel more at ease, researchers are available to provide a list of the questions that will be used in the interview. The interview will be conducted by a researcher/interviewer with appropriate training and will be preceded by the signing of the consent form for participation in the research and the indication of:

- the duration of the interview.
- the need for the interview to be audio-recorded, subject to the participant's consent.
- the deletion of the audio track, after its transcription and anonymization, subject to the participant's consent.

Opening the interview: Open-ended questions will be asked to put the interviewee at ease (ice-breaking questions). For example: “Thank you for participating. I wanted to ask if you have any questions for me? Are there any doubts?”

Conducting the interview

- "If you brought the photograph, let's discuss it together. Try to ‘think out loud’ as you answer my questions.
- “What was it like for you to choose this photograph?”
- “When you look at it, what do you think about?”
- “How does the photograph relate to your experience at the ARCADE clinic?”

If the participant chooses not to bring the photograph, the interview will begin with: “Try to ‘think out loud’ as you answer my questions.” In any case, the interview will continue with the following questions:

- “Can you tell me about your experience with the service? How did you find out about it? What did you think?”
- “What did it involve”?
- “How did you feel”?
- “With regard to your body, could you tell me your thoughts from the beginning of treatment to today?”

Closing the interview

- “How would you rate the service you received?”
- “How could it be improved?”
- “Is there anything else you would like to say about what has been discussed?”

Thank you and turn off the recording.

Appendix C – Final procedure

Part 1: NAC tattooing fist access.

Activity	Description	Time	Operator
Taking in charge	Collection of medical history and general information. Obtaining informed consent for the treatment and for photographic documentation. Photo before the treatment.	10 min	Nurse
Reconstruction planning	<p>With surgically reconstructed nipple:</p> <ul style="list-style-type: none"> - Study of the shape of the contralateral areola for mirror reproduction. - Identification of specific features to reproduce for greater personalization (skin lines, tubercles, areas of lighter or more intense color). - Creation of the areola-nipple complex. - Symmetry assessment. <p>Without surgically reconstructed nipple:</p> <ul style="list-style-type: none"> - Identification of reference points. - Drawing reference points for the design. - Creation of the areola-nipple complex following the previously identified lines and points. - Symmetry assessment. 	20–30 min	Nurse (+ plastic surgeon if necessary)
Application of anesthetic cream to intact skin	Application of anesthetic cream to the area identified during the initial planning. Covering with transparent film/patch to ensure greater comfort during the wait and to help operators identify the most suitable color for mixing.	30 min waiting after application	Nurse
Color selection	During the wait for the anesthetic cream, color tests are performed to identify the shade that most closely matches the contralateral complex, if present.	—	Nurse

Dermopigmentation session	<p>Removal of anesthetic cream.</p> <p>Disinfection of the skin.</p> <p>Application of fenestrated drape.</p> <p>The trained nurse may decide whether to start tattooing the areola or the nipple based on the evaluations made during planning, which will affect the sequence of needles and color mixtures used.</p> <p>The areola-nipple complex is reproduced using a 3D (light-dark) technique, inserting bioresorbable pigments into the epidermis with disposable needles. The instrument used is the dermograph.</p> <p>The technique is performed aseptically, maintaining correct needle depth and excursion, dermograph angle, and 3D effect.</p> <p>Photo after the treatment.</p>	<p>45 min (unilateral); 80 min (bilateral)</p>	Nurse
Dressing and post-treatment instructions	<p>Application of fatty gauze and flat/regular dressing.</p> <p>Information (explained and provided via brochure): at the end, the area must be cared for like any wound. The nurse will leave a fatty gauze in place, to be removed after about 3 hours. At home, patients should regularly clean the new areola with water and mild soap, dabbing rather than rubbing. Application of an emollient cream is recommended for 3–4 days, 1–2 times a day or as needed. Small scabs may form in the following days, which should be left until they fall off naturally (about 10–15 days). During this period, avoid swimming pools, saunas, steam baths, intense sports, tight clothing, synthetic materials, and sun exposure.</p> <p>Scheduling the next session.</p>	5 min	Nurse

Part 2: NAC tattooing subsequent accesses

Activity	Description	Time	Operator
Welcome and Taking in Charge	Collection of feedback regarding healing from the first treatment, any problems, and the degree of adherence to the instructions provided. Photo before the treatment.	10 min	Nurse
Application of Anesthetic Cream to Intact Skin	See Part 1.	30 minutes waiting after application.	Nurse
Dermopigmentation Session	See Part 1.	35 min (unilateral) 60 min (bilateral)	Nurse
Dressing and Post-Treatment Instructions	Application of the remaining color mixture with gauze on top, solely to avoid staining personal clothing. Information: see Table 1. Scheduling the next session and/or annual follow-up.	5 min	Nurse