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Interdisciplinary Journal of Nursing and Health (IJNH) is a continuation of *Infermieristica Journal (eISSN 2785-7018).*
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Editorial

OPEN ACCESS

Beyond Disciplinary Silos: The Power of Interdisciplinary Care and Research

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Mario's history

Mario is 78 years old and has been living with type 2 diabetes for over 20 years. His most recent HbA1c is slightly above target, and his treatment plan appears straightforward on paper: metformin and an insulin injection each evening. But Mario's situation is a bit complex. He lives alone and has mild cognitive impairment, which sometimes makes it difficult for him to remember whether he has already taken his evening insulin; some days he takes it twice. He also suffers from peripheral neuropathy, which has reduced sensation in his feet, so a small blister from an ill-fitting shoe went unnoticed for days before becoming an open wound. One evening, Mario administered two insulin injections without realising it. The following day, he experienced an unrecognised episode of hypoglycemia and fell home. Since then, he has become anxious about walking outside, moving less and eating irregularly, making his glucose levels even more difficult to predict.

Disciplines around Mario

In this complex situation, we could think that nursing could help Mario cope. But Mario also needs the work of many other disciplines: Diabetology, to reassess his insulin regimen in light of his recent hypoglycemic episode; podiatry, to treat his foot wound; physiotherapy, to address his risk of fall and rebuild his confidence in moving safely; and social work, to reduce his isolation and connect him with the community support he needs.

Good prescriptions

In practice, all of these specialists may visit Mario, examine him carefully, and each issue their own "good prescription". The nurse could educate Mario to diabetes self-care, to properly administer insulin and be aware of the first symptoms of hypoglycemia; the diabetologist, mindful of Mario's recent hypoglycemic episode, could appropriately re-establishes his insulin dose and diet; the podiatrist could prescribe special shoes; the physiotherapist could prescribe resistance exercises and balance training, to rebuild the muscle strength and confidence he lost after becoming afraid to walk outside; finally, the social worker could suggest Mario to live less in isolation and to meet other people in the neighborhood. Mario has received good prescriptions from many disciplines, yet his problems remain. Together, without coordination, all these specialists have

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even made Mario's life more complex.

Controlling for confounders

In research, we find similar situations when different disciplines work alone. The result is not many prescriptions as in Mario's history, but incomplete evidence, each valid within its own frame but insufficient to explain the phenomenon as a whole.

Let us consider research on falls among older adults with diabetes, a problem that, much like Mario's case, does not belong to any single discipline. A nursing study may focus on medication adherence and self-care behaviours, examining how missed or duplicated insulin doses contribute to falls, with recommendations centred on monitoring and patient education. A diabetology study, working independently, can instead identify hypoglycemia and glycaemic variability as the main drivers of falls, designing its analysis, variables, and recommendations entirely around glucose control. A podiatry study, in turn, may indicate neuropathy and altered gait mechanics attributed to falls, to loss of sensation and impaired proprioception on the feet. Instead, a physiotherapy study may emphasise muscle weakness and poor balance, proposing strength and balance training as the primary solution. And a social work study can highlight living alone and social isolation as the underlying risk factors, with recommendations centred on community resources. Each of these studies, read on its own, offers a coherent and well-supported explanation. However, each is incomplete.

The danger is not that any of these findings is wrong. The reason is that none of them alone can account for how these factors interact in a real person's life. A patient like Mario does not fall because of hypoglycemia, or insufficient self-care, or because of cognitive impairment, or because of neuropathy: he falls because all these factors converge and amplify one another. When research is conducted in disciplinary silos, Mario's real, lived experience remains invisible. Each discipline measures its own variables, controls for the others as "confounders" to be adjusted away, and publishes within its own journals. Disciplines evolve, but Mario's problems remain.

The power of interdisciplinary approaches

An interdisciplinary approach in clinical practice and in science is different. A first example could be the study by Zhuang et al. (2025). In this trial, which enrolled 216 hospitalized older patients with type 2 diabetes, participants were randomly assigned to receive either standard care, with specialists working in silos, or interdisciplinary care with different specialists working together. After 26 weeks, the results were clear: patients in the interdisciplinary group showed significant improvements not only in glycaemic control, measured by fasting blood glucose and HbA1c, but also in body mass index, lipid profiles and renal function, compared to those who received standard care in silos. Almost as importantly, their quality of life improved in several dimensions, including emotional function, vitality, and social functioning.

A second example comes from Ireland (Cassarino et al., 2021), where researchers tested whether an interdisciplinary team could improve the care of older adults in a very different setting: the emergency department (ED). Older adults are frequent ED users and their visits are often marked by complex, overlapping needs that a single clinician has little time to fully address during an acute presentation. In this single-site randomised controlled trial, 353 patients aged 65 and older, with lower urgent complaints at a university hospital in Ireland, were randomly assigned to receive regular ED care or early assessment and intervention by a dedicated interdisciplinary team of health and social care professionals (a social worker, an occupational therapist, and a physiotherapist) working together rather than being consulted separately. The results showed that this coordinated interdisciplinary assessment reduced the length of stay in the emergency department, lowered the risk of hospital admission, and improved patient satisfaction, compared to standard care. As with Mario, the point was not that any single discipline was missing from usual care but that bringing these disciplines together, working jointly from the moment of assessment rather than in sequence, changed the outcome itself.

The above single studies are only two examples, but we have even stronger evidence synthesised in systematic reviews and meta-analyses (Xu et al., 2024). A 2024 systematic review and meta-analysis pooled data from 18

randomized controlled trials to evaluate the effect of comprehensive geriatric assessment, an interdisciplinary diagnostic and care-planning process, much like the one Mario would need, on older adults with frailty in hospital settings. The results showed that patients who received this coordinated multidimensional assessment had a significantly lower risk of death compared to those receiving standard care. They also showed a reduced risk of losing independence in daily activities compared to usual care.

All this evidence says that when disciplines assess and plan care together around the same person, rather than issuing separate, uncoordinated prescriptions, as happened initially with Mario, the benefit is not marginal or theoretical: it can be measured in lives saved and independence preserved.

Why is collaboration so hard?

If an interdisciplinary approach is so productive in terms of patient outcomes, why do disciplines struggle to work together? The literature itself offers an answer (Wei et al., 2022). A 2022 systematic meta-review, synthesising 36 systematic reviews on interprofessional collaboration in healthcare, identified barriers operating at three distinct levels: organisational, team, and individual. At the organisational level, rigid hierarchies, competing priorities, and a lack of institutional structures for shared decision-making make coordination difficult before clinicians even meet. At the team level, unclear role definitions and professional "silos", with each discipline sticking to its own function, limit the kind of ongoing communication that Mario's case would require. At the individual level, deeply ingrained professional hierarchies still shape everyday practice: a nurse may hesitate to question a physician's decision, a junior clinician may stay silent in front of senior colleagues, and each professional may simply assume that other disciplines are already aware of their reasoning, when in fact they could not. None of this reflects a lack of competence or goodwill. It reflects the fact that health systems and often the education that trains health professionals have historically been built around single disciplines working in parallel and not around a structured integration that patients like Mario actually need.

Building the conditions for collaboration

Fortunately, this is not an unaddressed problem. Several models and frameworks, developed over the past two decades, offer concrete guidance on how to move from disciplines working in parallel to disciplines working together. The World Health Organization's Framework for Action on Interprofessional Education and Collaborative Practice, published in 2010, remains the most widely referenced starting point (World Health Organization, 2010—Figure 1). It calls on policy-makers, educators, and health workers to embed interprofessional education and collaborative practice into the services they deliver, arguing that fragmented, single-discipline systems must be redesigned around teams if healthcare is to respond adequately to complex patient needs. At a more theoretical level, D'Amour and colleagues (2005) proposed a model of collaboration that identifies the conditions collaboration actually depends on: a shared vision of the patient's goals, mutual acknowledgment of each other's expertise, clear governance of how decisions are made, and formal structures, such as shared protocols and documentation, that make coordination possible rather than incidental. Applied to Mario's case, this model helps explain precisely what was missing: not clinical competence, which none of his specialists lacked, but the shared vision and formal structures that would have let his nurse, diabetologist, podiatrist, physiotherapist, and social worker build one coherent plan instead of six separate ones. These frameworks converge on the same conclusion: interdisciplinary collaboration is not simply a matter of goodwill or proximity. It is a competency that can be defined, taught, and structurally supported. Its absence, as Mario's case shows, is not a personal failing of any single clinician but a systemic gap that health systems, and the education that prepares health professionals, must deliberately close.

The Role of IJNH

When we developed the *Interdisciplinary Journal of Nursing and Health* (IJNH), our idea was that the product of more disciplines working together is more than the product of every single discipline. This is precisely the space for which

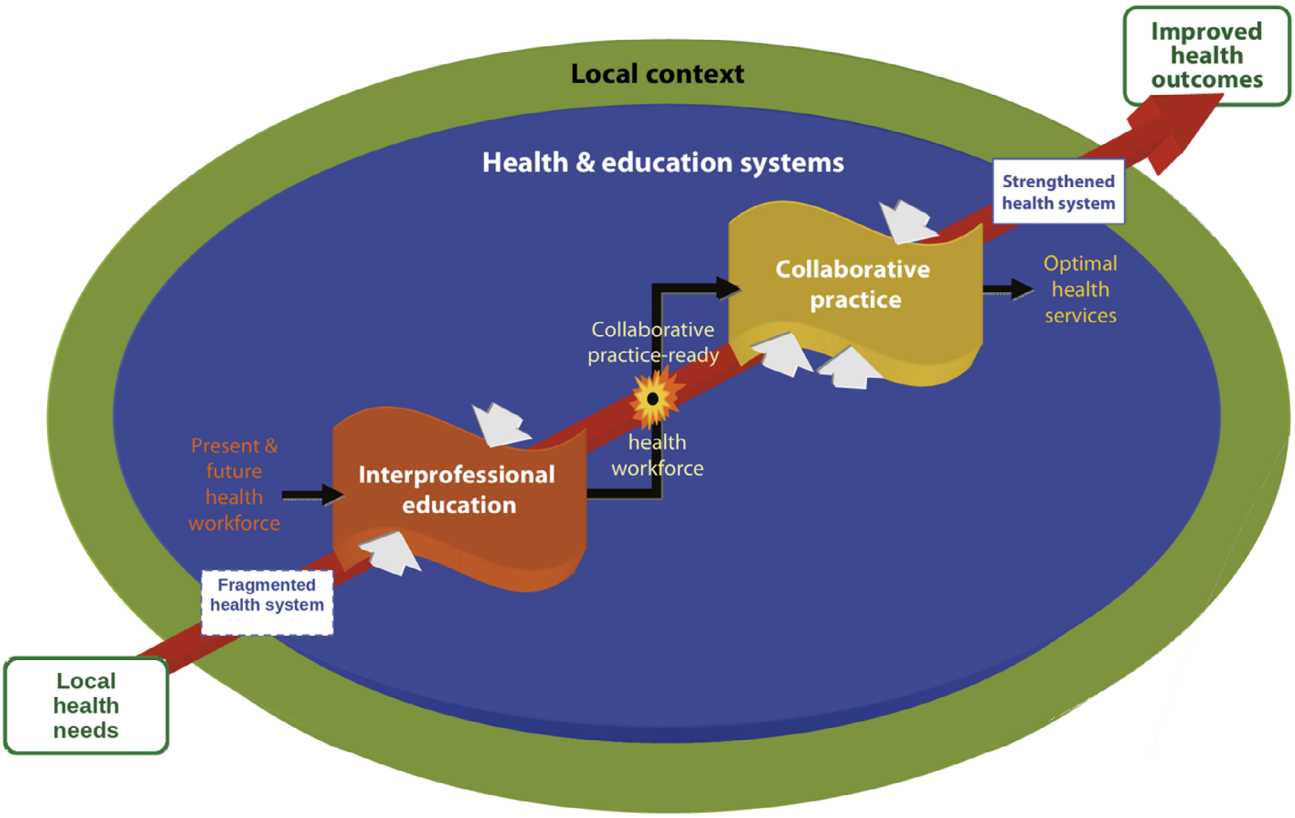


Figure 1. The WHO framework for interprofessional education and collaboration.
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the IJNH was created. When we launched this journal, our founding editorial (Vellone et al., 2025) stated that health is not the exclusive domain of any single profession, but the intersection of biological, psychological, social, cultural, economic and environmental factors, and that isolated disciplinary approaches are insufficient to address the challenges of our time. Mario's case is a concrete illustration of exactly this claim: his story could not be fully told, let alone resolved, within the pages of a single-discipline journal.

The contribution of IJNH's to the field lies precisely in refusing that fragmentation. We actively welcome and seek research that bridges nursing, medicine, psychology, sociology, public health, pharmacy, rehabilitation sciences, and beyond, not as separate submissions filed under separate headings, but as scholarship that speaks across these boundaries in a single integrated voice. This does not mean that we have already achieved this objective, but we are moving forward ...

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Commentary

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Vocation in Healthcare Professions: Between Philosophical Legacy and Contemporary Challenges

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The term vocation derives from the Latin vocatio, meaning "call" or "invitation" (Rahner, 1977). Originally, it referred to a religious experience in which an individual responded to a divine mission. This meaning became central in the Christian tradition, from Augustine of Hippo to Thomas Aquinas, and gradually expanded into secular and professional contexts. The Christian tradition represents the historically dominant framework in the Western context within which the healthcare professions first elaborated their professional self-understanding. Yet the call to care is not the exclusive property of any single tradition. Parallel and equally rich conceptions exist in Islamic medical ethics, in Buddhist notions of compassionate service, and in secular humanist framework, each offering distinct but convergent grounds for vocational dedication in healthcare. A comparative analysis of these traditions lies beyond the scope of this article; what matters here is the recognition that vocation, as a human response to the call to care, is neither culturally bound nor historically exhausted.

Over the centuries, especially with the onset of modernity, this concept underwent a significant semantic and existential transformation. It lost part of its transcendent connotation and came to signify a meaningful choice: not a predetermined destiny, but a direction built over time through freedom, authenticity, and responsibility. The term "modernity" is used here in the sociological and philosophical sense: the structural transformation of Western societies initiated by the Enlightenment and accelerated by secularization, rationalization, and the differentiation of social spheres, a process analyzed most influentially by Weber (1965) and Taylor (1993). It does not denote the contemporary period generically, nor is it assumed to be universally generalizable; rather, it designates the specific historical horizon within which the professional understanding of vocation emerged and was theorized in the literature this article draws upon (Taylor, 1993).

Vocation is not a concept exclusive to the healthcare professions. Contemporary psychological and organizational research, most systematically developed by Dik and Duffy documents the sense of calling across a wide range of occupations: teaching, academic research, social work, environmental professions (Dik & Duffy, 2009). In this respect, vocation belongs to the human condition more broadly than to any specific professional category (Husserl, 2002). Yet in the caring professions

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it takes on a qualitatively distinct form. Daily contact with suffering, vulnerability, and the limits of human life introduces an existential dimension that few other professions share with the same structural intensity. This is not merely a question of finding meaning in one's work, but of confronting the other in their most profound fragility, day after day. That exposure is not incidental: it is constitutive of the act of care itself, and it transforms healthcare vocation into something that exceeds simple professional motivation. A further dimension deserves consideration: the cultural one. The concept of vocation crosses cultural boundaries, but the way it is experienced, expressed, and transmitted is deeply shaped by the context of belonging, religious, social, historical. In some traditions the call retains an explicitly spiritual connotation; in others, an ethical and prosocial reading prevails. Empirical research on this variability remains limited, but to ignore it would mean treating vocation as an abstract universal, stripping it of the very concreteness that makes it relevant for those who care (White, 2002).

A related question concerns the fate of the transcendent dimension. It is tempting to state that vocation has lost its transcendent connotation, and the original text of this article did so. Yet the scientific literature does not support this claim in any unequivocal way, and precision here matters. Contemporary debate distinguishes two main positions. The neoclassical approach, defended among others by Duffy and Dik (2013), maintains that vocation retains a component of external summons: a call perceived as coming from something beyond the individual. This source need not be God or a deity; it can be the need of society, a sense of destiny, or a moral imperative felt as external to the self. Transcendence, in this reading, does not disappear with secularization, it transforms (Husserl, 2002). More contemporary approaches, by contrast, tend to relocate the source of vocation within the individual: the drive toward self-realization, coherence with one's values, the desire to contribute. Even here, however, a dimension that transcends personal interest persists, the reference to the other, to the community, to the common good. What empirical research calls into question is the assumption, often implicit, that the secularized version of calling has simply replaced the religious one. Evidence for this substitution is insufficient (White, 2002). What emerges instead is coexistence: in the healthcare professions today, those who experience their dedication in explicitly spiritual terms live alongside those who ground it in lay values of justice, care, and responsibility. Both forms are authentically vocational. For healthcare professionals, this distinction is not merely academic. It means that vocation can be reduced neither to a religious residue to be overcome, nor to a simple intrinsic motivation to be captured by psychometric scales. It is a complex existential orientation, integrating meaning, relationship, responsibility, and, in many lived experiences, still some form of transcendence, whether lay or religious.

In healthcare professions, this complexity is particularly evident. The concept of vocation has undergone a paradigm shift: the "sacrifice model", in which the healthcare professional was expected to subordinate personal needs to an almost devotional ideal of service—has progressively given way to a "commitment model," in which vocation is understood as a conscious and responsible choice to direct one's skills, time, and emotions toward the care of others. What has changed is not the depth of dedication, but its foundation: no longer self-abnegation, but autonomous ethical engagement. This shift is documented in the empirical literature on calling, which identifies meaning, prosocial orientation, and identity coherence, rather than sacrifice, as the core dimensions of vocational experience in contemporary healthcare professionals. It is a commitment to a way of being, even before a response to a profession. A way of existing in the world with the intent to preserve, accompany, and alleviate.

Edmund Husserl, father of phenomenology, helps us explore this dynamic more deeply. According to his framework, vocation is not passively received, but emerges as an intentional act rooted in the lived experience of authentic values. Vocational action, in this sense, is not driven by utility but by goodness. It results from an internal tension expressed in concrete action and relationships with others (Husserl, 2002).

A related perspective is offered by White's analysis of nursing as vocation, which conceives of the call not merely as a specific response to a profession but as a broader life project, a personal journey of growth shaped by ongoing choices and transformations. In this view, vocation leads individuals to discover their unique role in the world and to contribute to the

common good (White, 2002). Importantly, this framing allows for a conceptual detachment of nursing vocation from its historically feminine connotation. For much of its history, nursing has been understood through the lens of "natural" female qualities, care, self-sacrifice, docility, a characterization that both idealized and constrained the profession. Grounding vocation instead in ideals of social responsibility, moral commitment, and ethical engagement shifts the foundation: the call is not to a gendered role but to a human project. Gender remains a dimension worth considering—research suggests that men and women may experience and narrate their sense of calling differently, and that institutional cultures can shape these experiences in ways that merit attention (Evans, 1997), but it ceases to be the defining criterion of vocational suitability.

In healthcare, this vision translates into the ability to integrate technical knowledge with ethical personal motivation. Caring is not only action, it is also intention, meaning, and orientation toward the other (Heinämaa, 2020, 2023).

This emphasis on phenomenology carries methodological implications that deserve to be made explicit. If healthcare action is not reducible to technique, if it involves intention, meaning, and relationship, then research designed to understand and develop it cannot be limited to positivist frameworks alone. There is a need for studies capable of capturing the epistemological content of specific professional knowledge: the forms of knowing embedded in practice, in clinical judgment, in the relational dimension of care. This does not mean abandoning scientific rigor; it means expanding the conception of what counts as evidence. Phenomenological inquiry, narrative research, and qualitative methodologies offer tools to illuminate aspects of professional knowledge that quantitative measurement alone cannot reach (Benner, 2003; Lincoln & Guba, 1985). Acknowledging this is not a retreat from science, it is a more honest account of what professional expertise actually is.

Thus, competence becomes not only technical but also ethical, reflective, and narrative. It is not enough to know how to intervene; one must also understand why.

This why is not merely theoretical, it is deeply embodied and constructed over time. As Polanyi would suggest, it is a form of personal knowledge involving body, emotions, and experience; it is composed of intuition, memory, and sensitivity. This type of knowledge resists measurement but transforms every technical act into a human act (Polanyi, 1966).

This understanding of knowledge as embodied and personal raises a further question that deserves explicit treatment: what is the relationship between vocation and the development of professional knowledge? The two dimensions are not parallel but deeply intertwined. Vocation sustains the motivation to learn, to question, to go beyond the merely procedural. It is what keeps curiosity alive in the face of complexity and what makes professional development not a bureaucratic obligation but a personal and ethical commitment. Conversely, the growth of knowledge nourishes vocation: a healthcare professional who deepens their understanding of the person, of pathophysiology, of care relationships, finds in that knowledge new reasons to remain present and engaged (Benner, 2003; Eraut, 1994). Vocation without knowledge risks becoming mere sentiment; knowledge without vocation risks becoming a cold technique applied to passive bodies. Their integration is what defines a genuinely professional act.

In this regard, Husserl also emphasizes the temporal dimension of vocation, which links past, present, and future—a pattern well reflected in the healthcare tradition of intergenerational transmission of knowledge and values (Manca, 2018; Moran, 2011).

This temporal dimension of vocation opens a question that the text has so far left implicit: when we speak of phenomenology as a transformative lens for healthcare, are we referring to all healthcare professions, or primarily to nursing? A clarification is warranted. The text has repeatedly invoked phenomenology as a transformative lens for understanding healthcare action. But the question arises: has the phenomenological perspective influenced the transformation of healthcare professions broadly, or primarily nursing? The honest answer is that its impact has been uneven. In nursing, phenomenology has played a particularly generative role, shaping theoretical frameworks, clinical methodologies, and professional identity in ways that are well documented in the literature. In other healthcare professions, its influence has been more limited, though not absent (van Manen, 1990). What phenomenology has offered across

disciplines is a shift in the fundamental question: from what is done to how it is experienced, by the professional, by the patient, by both in relation. This reorientation has changed the way phenomena such as pain, vulnerability, clinical communication, and decision-making are studied and understood. It does not replace the positivist contribution; it complements and deepens it.

It is through narrated transmission that vocation persists and endures. As Ricoeur suggests, human beings are narrative subjects: we construct identity through the stories we tell about our experiences. Vocation is one of these stories, one that gives biographical coherence, connects past and future, and transforms everyday practice into a meaningful narrative (Ricoeur, 1993). It is not static, but a process, a becoming. Each choice and each relationship contribute to writing this story and, in doing so, restore the deeper dimension of healthcare work.

Kierkegaard, from his existential perspective, offers a compelling interpretation of vocation as a radical choice. One is not born called; one chooses to become so, often amidst difficulties, uncertainties, and responsibilities. It is a call renewed daily, one that can be questioned but, if recognized as authentic, becomes an inner strength. In this light, healthcare professionals continually choose to remain present, even when systems are unsupportive, even in adverse conditions. It is an act of freedom but also of fidelity to oneself. (Kierkegaard's analysis in this work centres on anxiety and the psychology of freedom rather than on professional vocation per se; the reference here draws on the broader existential framework he develops, in the interdisciplinary tradition of applying his thought to questions of identity and commitment in professional life) (Kierkegaard, 1984). This understanding of vocation as an evolving construction finds qualified support in the exploratory work of Hey and Nowakowski (an academic thesis rather than a real study, and therefore indicative rather than conclusive), who interviewed physicians and dentists at different career stages and found that all participants described their sense of calling as something that had transformed over time, shaped by professional experience, personal growth, and the accumulated weight of clinical encounters (Hey & Nowakowski, 2013).

However, this idea of vocation is not without risks. Recent history offers a powerful reminder. During the COVID-19 pandemic, the world witnessed an extraordinary display of dedication by healthcare professionals. They were hailed as heroes, angels, and missionaries. Before turning to the risks, it is worth pausing on what this dedication actually was: an act of freedom and moral responsibility. Healthcare professionals chose to remain present, in conditions of extreme personal risk, institutional uncertainty, and social upheaval, not because they were compelled to, but because their vocational orientation made withdrawal inconceivable. The pandemic did not create this commitment; it revealed it. In this sense, the COVID-19 experience is one of the most powerful empirical demonstrations of what vocation means in practice: a freely renewed choice, sustained by identity, meaning, and responsibility toward the other. But the heroic rhetoric surrounding this dedication also introduced a subtle danger: the instrumentalization of vocation (Čartolovni et al., 2021). When commitment becomes a justification for inadequate protections, excessive workloads, or unrecognized sacrifices, vocation turns into a burden, a moral trap (Broome et al., 2024). This is why it must be protected: through sound health policies, ongoing education, and social recognition. Otherwise, vocation risks fading or becoming self-destructive, leading to burnout and disillusionment (Kar, 2020). A recent systematic review by Hernández-Xumet and colleagues confirms this picture: vocation functions as a powerful initial motivator, but its persistence requires sustained meaning-making, self-care strategies, and a training environment that actively supports it, conditions that are far from guaranteed in contemporary healthcare systems (Hernández-Xumet et al., 2025a).

Weber had already grasped this tension. In his analysis of modernity, he described Beruf (vocation-profession) as responsible action in a disenchanted world, but he also warned of the danger that efficiency, bureaucracy, and rationalization might strip this action of meaning (Weber, 1965). Today, this risk is real in healthcare: procedural logic and fragmented work threaten vocational passion. There is, therefore, an urgent need to rediscover the meaning that makes caregiving valuable, not just a matter of time management.

The hermeneutic tradition reminds us that every meaning, including the meaning of vocation, is transmitted through culture,

language, and historical horizon. In this sense, dedication to care as a form of vocation is not an invention of any single tradition but a recurring human response, expressed in different forms across societies and historical periods (Gadamer, 2001). Even in contemporary societies marked by fragmentation, signs of renewal are emerging.

Younger generations demonstrate new sensibilities: attention to the environment, well-being, and inclusivity. If adequately supported, they may rediscover vocation not as a duty but as an opportunity, to live their work as an expression of values, as a space to impact others' lives with authenticity (Dimock, 2019; Williams, 2020). Empirical evidence supports this reading: a cross-sectional study among nursing and physiotherapy students found that vocation for human care correlates positively with empathy and assertiveness, suggesting that these dimensions reinforce one another and that vocational orientation is already measurable and meaningful at the formative stage (Hernández-Xumet et al., 2025b).

From here, a renewal of vocation becomes imaginable, not as a nostalgic return to idealized models but as a reinterpretation aligned with contemporary complexities. A vocation that embraces fragility, resists pressure without losing its integrity; one that demands not perfection, but coherence. One that does not impose sacrifice but values dedication (Morgan, 2023).

One final knot deserves to be untied: the relationship between the transformation of professional vision and the mission of healthcare disciplines, and, within this, the question of foundational knowledge. If vocation is understood as consistent with mission, as this article has argued, then what are the epistemic foundations that sustain it? Healthcare professions occupy a complex epistemological space. Their knowledge is partly anchored in medicine and the biomedical sciences; partly rooted in the social, human, and psychological disciplines; and increasingly, though still haltingly, defined by bodies of knowledge specific to each profession. Nursing, to take the most developed example, has worked for decades to identify its own theoretical frameworks, its own objects of inquiry, its own research methodologies. The same path is being traced, at different speeds and with different degrees of institutional recognition, by the other healthcare professions (Meleis, 2012). Vocation, in this context, is not separable from the question of knowledge: to choose a healthcare profession is also, implicitly or explicitly, to commit to contributing to the development of that profession's understanding of itself. It is a call not only to care, but to know, to question, and to build.

A contemporary vocational model should be grounded in four dimensions:

- Personal ethics: Healthcare as a conscious and responsible choice;
- Community and generations: Continuity between tradition and innovation;
- Narrative and meaning: Constructing meaning through practice;
- Cultural pluralism: Openness to diverse understandings of care and health.

Vocation in healthcare is not an outdated concept but a strategic resource to address today's challenges. Through the lenses of phenomenology, philosophy, and culture, it emerges as an ethical and existential engine that gives meaning to healthcare work, fostering both individual and collective well-being.

Re-centering vocation in healthcare education and organization means reconstructing a social pact based on trust, care, and shared meaning. Because ultimately, every act of care is also a response to the fundamental question of why one chooses a healthcare profession. And every authentic response is already a vocational act. This includes the technical act itself. One of the most important tasks ahead, for research, for education, and for professional culture, is to demonstrate that the nursing gesture, the clinical procedure, the diagnostic reasoning are not vocationally neutral activities onto which meaning is later projected from the outside. They are already, in themselves, the site where knowledge, relationship, and ethical commitment converge. A dressing change performed with presence and competence, a medication administered with attention to the person's experience, a clinical handover conducted with precision and care for continuity: these are not merely technical acts. They are the concrete form that vocation takes in practice. Demonstrating their epistemological content, what they know, what they require, what they transmit, is not only a matter of professional recognition. It is the condition for vocation to remain, in healthcare, a living and generative force rather than a rhetorical inheritance.

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Study Protocol

OPEN ACCESS

Self-Care and Caregiver Contribution to Self-Care in Dyads Receiving Oral Anticancer Treatment (Dyads-in-Cancer): A Protocol for an Observational Longitudinal Study

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Abstract

Introduction. The use of oral anticancer agents (OAAs) has increased in recent years. These medications have many benefits, including improved tolerability, adaptability, and decreased stress compared to intravenous treatments. However, studies have shown that there are potential challenges with these treatments, including poor adherence and limited multidisciplinary support. As a result, it is important to focus on self-care behaviours for managing OAA treatment from a dyadic perspective. However, self-care levels in this population and the contribution of informal caregivers to self-care have yet to be extensively described, along with their predictors and outcomes. Therefore, the aim of this study is to describe a

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research protocol of a multicentre observational longitudinal study designed to investigate the self-care of patients with cancer taking OAAs and the caregivers' contribution to this self-care, and to examine the self-care predictors and outcomes.

Methods. This study will recruit patients with cancer undergoing OAA treatment and their informal caregivers. Data collection will include patient and caregiver sociodemographic factors, patient clinical information, patient self-care and caregiver contribution to self-care, variables at patient-, caregiver- and dyad-level that can predict self-care and caregiver contribution to self-care. We will also investigate whether self-care and caregiver contribution to self-care can predict important patient outcomes (e.g. emergency room access, rehospitalization, survival, quality of life) and/or caregiver outcomes (e.g. the positive aspects of caregiving). Data analyses will include descriptive statistics, regressions, ANOVAs, structural equation modelling, and dyadic analyses.

Discussion. This research will enhance the understanding of self-care in patients with cancer taking OAA and caregivers' contribution to self-care. It will provide insights on the factors that influence self-care and important outcomes. The findings of this study will inform future research and guide tailored interventions to improve patient self-care and caregiver support.

Keywords: Self-Care, Oral Anticancer Agents, Cancer Patients, Caregivers, Dyads

Introduction

In recent years, the use of oral anticancer agents (OAA) for treating cancer has increased, as well as the number of patients affected by cancer (Leong et al., 2021). The use of OAAs for patients with cancer has various benefits, including better tolerability, greater comfort, and adaptability to activities of daily living, and less stress associated with intravenous administration. Moreover, patients and their caregivers usually prefer OAAs because they can manage this treatment at home and avoid hospitalisation (Eek et al., 2016).

Although OAAs have several practical advantages, studies indicate that patients taking OAA are prone to experience poor adherence to treatment. This could be due to a lack of frequent communication with the multidisciplinary team (Given et al., 2011), managing adverse events alone, forgetfulness, depression, emotional distress, and side effects of medication (Barillet et al., 2015; Greer et al., 2016). As a result, patients receiving OAAs should develop adequate self-care skills to manage their therapy effectively.

Self-care (SC) is a process through which patients aim to maintain their physiological and emotional well-being despite their illness (SC maintenance). It involves monitoring for any signs or symptoms related to their illness and its treatment (SC monitoring), and taking action if they recognise any signs of relapse or worsening (SC management) (Riegel, Jaarsma, et al., 2012b). However, patients may sometimes struggle to perform SC on their own. In such cases, informal caregivers often step in to help them, playing an important role in contributing to SC. This is called caregiver contribution to self-care (CCSC), which involves actions to maintain the patient's physiological and emotional stability (caregiver contribution to SC maintenance), monitoring for any signs or symptoms of illness (caregiver contribution to SC monitoring), and recommending actions to the patient in case of worsening health (caregiver

contribution to SC management) (Vellone et al., 2019). Informal caregivers are individuals, typically family members or friends, who offer continuous care, frequently at home, to chronic patients with varying degrees of disability (Castro et al., 2023).

Patient SC and CCSC have been extensively studied in various chronic conditions, including heart failure (Antonio-Oriola et al., 2022; Ercole Vellone, Maddalena De Maria, et al., 2020), diabetes mellitus (Ausili et al., 2017), chronic obstructive pulmonary disease (Clari et al., 2017), as well as in the context of colostomy and urostomy (Villa et al., 2019). Investigators have found that patient SC and CCSC are interdependent and constitute a "dyadic phenomenon" in which patients' behaviours influence caregiver behaviours and vice versa. While the use of OAAs is widespread, there is still a lack of detailed description of patient SC and CCSC in this field (Di Nitto et al., 2022; Sollazzo et al., 2023). Furthermore, predictors and outcomes of these behaviours have yet to be clearly identified. This lack of knowledge may be because instruments to assess patient SC and CCSC have only recently been developed (Lacarbonara et al., 2023).

Although there is limited knowledge about patient SC and CCSC, the Middle-Range Theory of Self-Care of Chronic Illness (Ercole Vellone, Maddalena De Maria, et al., 2020) and the Theory of Caregiver Contribution to Self-Care in Heart Failure (Vellone et al., 2019) can provide essential insights into the predictors and outcomes of these processes from a dyadic perspective (Riegel, Jaarsma, et al., 2012a; Riegel, Lee, et al., 2012) (Figure 1). In this protocol, we propose a conceptual framework based on the above-mentioned theories and available evidence to better understand SC and CCSC among patients with cancer receiving OAAs.

Predictors of self-care

The factors that can influence SC in patients with cancer treated with OAAs can be related to the patients themselves, their caregivers, and the dyad (Figure 1). Predictors of patient-related self-care could include sociodemographic factors (e.g., age) and clinical characteristics (i.e., severity of cancer, cognitive status, and the number of medications taken), comorbidity, self-efficacy (Riegel, Lee, et al., 2012; Riegel et al., 2021), and patient-centeredness. There is currently no evidence in the literature regarding predictors of SC in patients being treated with OAAs. However, in other chronic conditions, it has been well-documented that certain sociodemographic characteristics such as age (Ausili et al., 2016; Ausili et al., 2018; Cocchieri et al., 2015; Vellone et al., 2017), gender (Cocchieri et al., 2015; Vellone et al., 2017), and education (Vellone et al., 2017) can impact SC. Additionally, the severity of the illness (Bidwell et al., 2015), the cognitive status of the patient (Li et al., 2017; Świątoniowska-Lonc et al., 2021), the number of medications taken (Ausili et al., 2016; Vellone et al., 2017), and the presence of other comorbidities have been found to predict patient SC (Buck et al., 2015; Dickson et al., 2011) in other chronic conditions. The researchers who study patients treated with OAAs focused only on the factors that were associated with adherence to treatment. However, adherence is just one aspect of SC. These investigators found that comorbidities were predictors of adherence, but they were unable to understand if more comorbid conditions alter or improve adherence (Ali et al., 2017; Blanchette et al., 2020; Corter et al., 2018; Iacorossi et al., 2016; Oke et al., 2018; Tinari et al., 2015; Yuan et al., 2020; Zahrina et al., 2014).

Self-efficacy has been shown to be associated with SC in patients experiencing chronic conditions (Juarez et al., 2021; Tan et al., 2021) and could play an important role also in SC behaviours for patients with cancer. Moreover, patient-centredness is another patient-related factor that can affect patient SC and the quality of care they receive (Epstein & Street, 2011). When patients feel the care is tailored to their unique needs and preferences (as a whole person), they are more likely to have positive outcomes, such as better quality of care, increased self-efficacy, and trust in their providers (Elkefi & Asan, 2023). We do not have evidence that patient-centredness could also improve patient SC in the context of OAAs, but a higher level of patient-centredness has been found associated with better cancer care (Riegel, Jaarsma, et al., 2012b), which is the distal goal of every SC programme.

Caregiver-related factors that can have an impact on patient SC and CCSC include sociodemographic characteristics, caregiver preparedness, caregiver burden, resilience,

and self-efficacy. Several previous studies in the context of chronic conditions have shown that caregivers who are younger, female, and married to the patient exhibit better CCSC (Bidwell et al., 2015; De Maria et al., 2023; Vellone, D'Agostino, et al., 2015). Additionally, caregiver preparedness has been found to positively influence patient SC and CCSC (Ercole Vellone, Valentina Biagioli, et al., 2020) in chronic diseases, but higher caregiver burden, lower resilience, and lower self-efficacy have been found to not influence SC and CCSC (Durante et al., 2022; Røen et al., 2018; Vellone, Fida, et al., 2015).

We have identified five dyad-related predictors of patient SC and CCSC from studies on chronic diseases. These variables are named dyad related as they are present in both patients and caregivers. They include social support, depressive state, dual symptom management, mutuality, and generic SC and CCSC. Several studies have found lower levels of SC and CCSC when patients and caregivers receive poor social support (Ausili et al., 2018; Freedland et al., 2021), are depressed (Dickson et al., 2011; Egede et al., 2009; Freedland et al., 2021; Riegel et al., 2011), not good at managing symptoms together (Buck et al., 2015; Dickson et al., 2011), and have less mutuality (Hooker et al., 2018; Vellone et al., 2018) (e.g., a worse relationship). We currently lack evidence to confirm whether generic SC and CCSC behaviours, as measured through instruments developed for all chronic conditions (e.g., follow the recommended diet) can predict SC and CCSC in patients with cancer receiving OAAs. However, we believe that individuals who engage in generic SC behaviours to manage their own health or that of their loved ones are more likely to perform the specific SC practices required to manage OAAs.

Overall, we know several predictors of patient SC and CCSC in chronic conditions, but we lack evidence on whether these predictors influence SC and CCSC in the context of patients with cancer treated with OAAs.

The process of SC and CCSC

The process of patient SC and CCSC includes three dimensions: (patients and caregiver contribution to) SC maintenance, SC monitoring, and SC management. These dimensions are all interdependent, either in the relationship between patients and caregivers (for example, patient SC maintenance may influence CCSC maintenance and vice versa). Moreover, each dimension (of patient's SC or

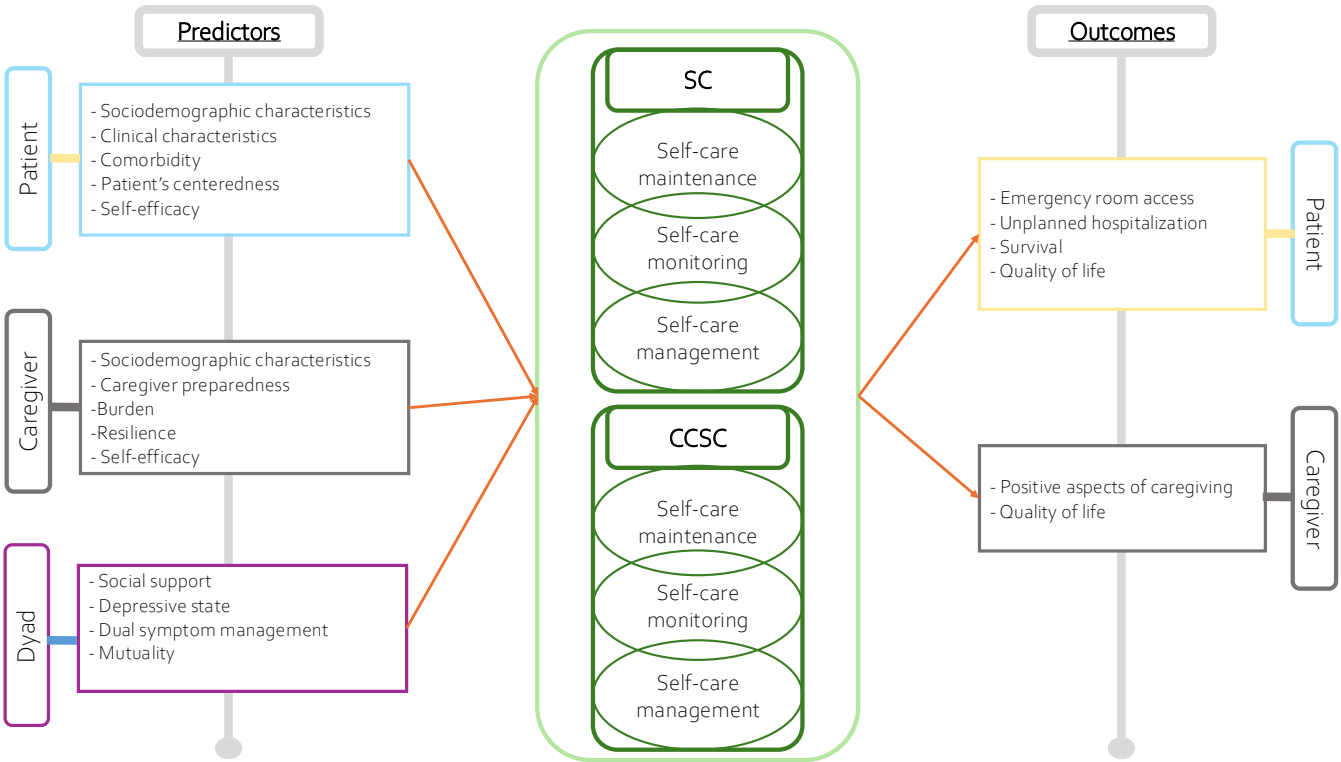


Figure 1. Theoretical framework of the study.

CCSC) can be related with the other one (e.g., SC maintenance with SC management, etc.). Specifically, in individuals with heart failure and chronic diseases (Ausili et al., 2016; Clari et al., 2017), the above three dimensions work in a sequential manner (e.g., SC maintenance influences SC monitoring and SC monitoring influences SC management). However, it is not yet clear whether this sequential relationship is confirmed in patients with cancer receiving OAAs. Moreover, in previous studies self-efficacy has been found to be a mediator between social support and SC (Iovino et al., 2023) but in patients with cancer this relationship has not been confirmed, and only one study examined the role of self-care as a mediator between self-efficacy and quality of life in patients with breast cancer receiving systemic chemotherapy (Chin et al., 2021).

Outcomes of self-care and caregiver contribution to self-care

The processes of SC and CCSC have been found to be associated with several positive outcomes related to the patient and caregiver. Studies conducted on other chronic diseases have shown that SC and CCSC can lead to improved quality of life for patients (QoL) (De Maria et al., 2019; Jovicic et al., 2006), reduced mortality rate (Gao et al., 2013; Kueh et al., 2015; Riegel et al., 2011), fewer hospitalisations (Jonkman et al., 2016), and fewer unplanned access to care (Clarke et al., 2017). Similarly, in the case of patients with cancer, studies have shown that inadequate SC behaviours (e.g. treatment non-adherence) can lead to significant worse outcomes, such worse symptom burden (Berry et al., 2015) and quality of life (Jacobs et al., 2019).

We have identified positive outcomes related to caregivers in our framework. These include positive aspects of caregiving and improved quality of life for caregivers. Studies on chronic diseases show that caregivers reported positive benefits of caregiving, such as self-affirmation and life enrichment (Cohen et al., 2002). In addition, higher confidence in CCSC was associated with better quality of life (Vellone et al., 2014). However, these outcomes have not been explored yet in the case of OAAs.

Aim

The aim of this study will be threefold: 1) to describe patient SC and CCSC in OAAs; 2) to identify predictors of patient SC and CCSC in the context of OAAs among patient- (e.g., sociodemographic and clinical characteristics, comorbidity, centeredness, self-efficacy), caregiver- (e.g., sociodemographic characteristics, preparedness, caregiver burden, resilience, self-efficacy), and dyadic-related variables (e.g., social support, depressive state, dual symptom management, mutuality, generic SC); 3) to examine patient and caregiver outcomes of patient SC and CCSC (e.g., patient emergency room access, unplanned hospitalisation, survival, quality of life; positive aspects of caregiving, quality of life).

Design / Methodology

This study will adopt a multicentre, longitudinal observational design.

Study procedures

Recruitment and setting

Data will be collected from five outpatient clinics in Italy, located in the three macro areas of the Italian territory (e.g., north, centre and south). A consecutive convenience sample of patients with cancer receiving OAAs and their informal caregivers will be enrolled. Participants, therefore, will be enrolled through non-probabilistic sampling. All patients visiting the outpatient clinics of the centres involved during the study period will be invited to participate in the study. All individuals who meet the inclusion criteria will be enrolled in the study (see below). Trained research assistants will explain the purpose of the study to all potential participants, and those who agree to participate will be asked to sign an informed consent form. Afterwards, participants (both patients and caregivers) will be asked to complete the study tool battery at enrolment (T0), after 3 months (T1) and after 6 months (T2) of enrolment. The informal caregiver will be asked about any unscheduled admission to the emergency room, rehospitalisation, or death of the patient at T1 and T2. The recruitment started in November 2022 and is planned to end by December 2025.

Inclusion and exclusion criteria

Patient inclusion criteria are: (1) adult patients (≥ 18 years); (2) ability to give informed consent; (3) diagnosis of a metastasised or locally advanced solid tumour; (4) understanding of the Italian language; (5) active treatment with OAAs (conventional chemotherapy, molecular targeted therapy, hormone therapy) started since at least 3 months. This interval was chosen because individuals with metastatic cancer typically have a short prognosis, as their clinical status might deteriorate quickly. Patients will be excluded if they have a diagnosis of haematological malignancy or serious cognitive impairment which could prevent them from understanding the meaning of the items.

Caregiver inclusion criteria are: (1) adult subjects (≥ 18 years); (2) ability to give informed consent; (3) understanding of the Italian language; (4) indicated by the patient as the main caregiver (in the case of more than one caregiver). Caregivers will be excluded if they receive any form of payment for their caregiving activities.

Instruments for measuring the predictors of self-care

Instruments for patient-related predictors of self-care

Sociodemographic and clinical characteristics of patients with cancer (e.g., age, sex, tumour site) and sociodemographic characteristics of caregivers (e.g., age, gender) will be collected using a specific questionnaire developed by the research team.

Comorbidity will be assessed with the Self-Administered Comorbidity Questionnaire (Sangha et al., 2003). This instrument consists of 12 items representing 12 medical conditions (e.g., hypertension, diabetes) and 3 optional conditions (e.g., not included in the 12 conditions). Participants will be asked to indicate whether– with yes or no - they have each condition, if they are receiving treatment for it, and if it limits their activities of daily living. Thus, an individual can receive a maximum of 3 points for each medical condition: 1 point for the presence of the problem, another point if he/she receives treatment for it, and an additional point if the problem causes a limitation in functioning. Since there are 12 defined medical problems and 3 optional conditions, the potential score ranges from 0 to 45.

The revised Patient Perception of Patient-Centeredness Questionnaire (PPPC-R) (Ryan et al., 2019) - is a valid and reliable instrument that measures patient centredness through the healthcare continuum. It includes 18 items and three factors: the healthcare process (items 1-8) (e.g., to what extent was your main problem(s) discussed today?), roles (items 9 and 10) (e.g., to what extent did you and your provider discuss your respective roles?) and context and relationship (items 11-18) (e.g., to what extent does your provider know about your family life?). Each item has a 4-point Likert scale, with responses ranging from 1 (very much) to 4 (not at all). The total score is the mean score of all items, with higher scores indicating a lower patient-centredness.

Instruments for caregiver-related predictors of self-care

The Caregiving Preparedness Scale (CPS) (Pucciarelli et al., 2016) is a valid and reliable instrument that consists of 8 items. The CPS measure the extent to which caregivers feel prepared in various aspects of caregiving (e.g., provision of physical care or emotional support). Each item has a 5-point Likert scale for responses ranging from 0 (not at all) to 4 (very much). The total score is computed by averaging all item scores. A higher CPS score means that the caregiver is better prepared.

The Caregiver Burden Inventory (CBI) (Novak & Guest, 1989) is a psychometrically sound instrument that will be used to measure caregiver burden. It comprises 24-items divided into five factors (e.g., time-dependent, developmental, physical, social, and emotional burden). The score can be calculated by adding up all the items, with a minimum of 0 and a maximum of 100 points (the physical burden score is multiplied by 1.5). Higher scores indicate a greater burden on the caregiver.

The Connor-Davidson Resilience Scale (Connor & Davidson, 2003; Ehrich et al., 2017) is a valid and reliable instrument that evaluates resilience as an individual's ability to cope with stress. This scale consists of 25-items (e.g., there is someone in my life who can help me

if I need), each scored from 1 (at all true) to 4 (almost always true). The score can range from 0 to 100, with higher scores indicating greater resilience.

Instruments for dyad-related predictors of self-care

Several valid and reliable instruments will be used to measure the same variables in both patients and caregivers in the dyads.

The Multidimensional Scale of Perceived Social Support (MSPSS) measures perceived social support. It is consisting of 12-items (e.g., my family is working hard to help me) with scores from 1 (strongly disagree) to 7 (strongly agree). The total score ranges from 12 to 84, with a higher score indicating a higher level of perceived social support (Zimet et al., 1988).

The Patient Health Questionnaire-9 (PHQ-9) (Arroll et al., 2010) will be used to assess patient and caregiver depression levels. The questionnaire comprises 9 items (e.g., feeling down, sad or desperate/a), with scores ranging from 0 to 27. Each item is rated on a scale from 0 (never) to 3 (almost every day). Scores between 5 and 9 indicate mild depression. Scores > 10 suggests a clinically significant level of depression.

Dyadic-type congruence in SC will be measured using the dual symptom management scale (Buck et al., 2019; H. G. Buck et al., 2013; Harleah G Buck et al., 2013), which assess how patients and their caregivers take care (e.g., decide what to do and how to do) of the patient's illness. Four categories of dyadic care can be obtained by administering the instrument to both members of the dyad: 1) patient orientated, when both members agree that the patient has the main role in managing the illness; 2) caregiver orientated, when both agree that the caregiver has the main role in managing the illness; 3) collaborative or complementary, when the patient and the caregiver agree to do the same things together or they divide them; 4) incongruent, when the patient and the caregiver do not give the same response (e.g. the patient reports that he/she has the main role in managing the illness and his/her caregiver reports a different response). A subsequent question assesses satisfaction with the management of the health-related problem. This question can be rated with a Likert scale ranging from 1 (extremely dissatisfied) to 5 (extremely satisfied). According to research, incongruent dyads tend to have worse outcomes (e.g., lower patient and caregiver quality of life) (Buck et al., 2018; Bugajski et al., 2021; Vellone et al., 2018).

The Mutuality Scale (MS) will be used to measure the quality of the relationship between the patient and the caregiver (e.g., how much does the person you assist help you?) (Archbold et al., 1990). The MS comprises 15 items rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (much). The total scale score is obtained by averaging the scores of all the items. A higher score on the scale indicates a better relationship quality between the patient and the caregivers.

Patients' self-efficacy will be measured using the Self-Care Self-Efficacy scale (SE-SC), which is a valid and reliable instrument consisting of 10 items. It aims to assess the extent to which patients feel confident in performing SC activities (e.g., confidence in following the prescribed treatment plan) (Di Nitto, Durante, et al., 2025). Each item uses a 5-point Likert scale for responses ranging from 1 to 5. The score is standardised from 0 to 100, and a higher score indicates greater self-efficacy.

Caregivers' self-efficacy will be measured using the Caregiver Self-Efficacy in Contributing to Patient Self-Care (CSE-CSC) Scale (De Maria et al., 2021), which is the caregiver version of the SE-SC with the same item and scoring format, but the language has been adjusted to fit caregivers' needs (e.g., confidence in doing something to alleviate patient symptoms). The CSE-CSC scale score ranges from 0 to 100, with higher scores indicating greater caregiver self-efficacy in contributing to patient SC.

Instruments for measuring the specific self-care processes

Specific SC behaviours will be measured using the Self-Care of Oral Anticancer Agents Index (SCOAAI), which is a valid and reliable instrument (Di Nitto, Ucciero, et al., 2025; Lacarbonara et al., 2023) assessing SC in patients with cancer treated with OAAs. This instrument comprises of 32 items which are grouped into three scales: SC maintenance (15 items) that assess behaviours that help maintain the patient's health (e.g. attend all medical visits as schedule); SC monitoring (11 items) that assess behaviours aimed at monitoring symptoms

associated with OAAs side effects (e.g. cancer medication side effects); SC management (6 items) that assesses behaviours implemented in the event of worsening symptoms associated with OAAs (e.g. contact the doctor or nurse to ask what to do in case of unmanageable symptoms). Each item in SCOAAI has a 5-point Likert response scale ranging from 1 (never) to 5 (always). Each scale has a standardised score ranging from 0 to 100, with a higher score indicating better SC.

The caregiver's role in patient SC will be measured using the Caregiver Contribution to Self-Care of Oral Anticancer Agents Index (CC-SCOAAI) (Di Nitto, Lacarbonara, et al., 2025). This index is specifically designed for caregivers and is based on the SCOAAI, consisting of 32 items. The only difference is that the CC-SCOAAI assesses the extent to which the caregiver recommends that patients perform SC behaviours (e.g., attending all medical visits as scheduled or monitoring cancer medication side effects). The CC-SCOAAI uses a 5-point Likert scale for responses (ranging from 1 never to 5 always) and provides a standardised score of 0–100. A higher score corresponds to better CCSC.

Generic SC behaviours will be measured using the Self-Care of Chronic Illness Index v.2 (SC-CII V.2) (Di Nitto, Durante, et al., 2025), which is an instrument developed and validated to measure SC in individuals with various chronic diseases. The tool consists of three separate scales that assess SC maintenance, SC monitoring, and SC management. Each item is rated on a 5-point Likert scale ranging from 1 (never) to 5 (always). On each scale, the score can range from 0 and 100, with a higher score indicating better SC. Scores > 70 indicate adequate SC. The Caregiver Contribution of Self-Care in Self-Care of Chronic Illness Inventory (CC-SC-CII) V. 2 was used to measure CCs to SC behaviours in chronic conditions (E. Vellone et al., 2020). This is a 19-item instrument consisting of three separate scales assessing SC maintenance (how often during the last month a caregiver recommended that the care recipient adopt those behaviours aimed at maintaining physical and mental stability of a chronic illness), SC monitoring (how often a caregiver recommended that the care recipient monitor signs and symptoms of their chronic illness), and SC management (how often a caregiver contributed to symptom recognition/interpretation and responded to symptoms of chronic illness exacerbation). Each scale is composed by 7 items, 5 items and 7 items, respectively. Each item of the CC-SC-CII is rated on a 5-point Likert scale ranging from 1 (never) to 5 (always).

Instruments to measure self-care outcomes

Patient-related outcomes

Several patient-related outcomes will be analysed to test the hypothesis that adequate SC behaviours can improve patient outcomes. Specifically, we will examine emergency room visits, unplanned hospitalisation, and survival rates, along with measuring QoL using the Core 30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) (Marzorati et al., 2019). This is a valid and reliable scale comprising 30 self-reported items that assess different aspects of patient functioning (e.g. physical, role, emotional, cognitive, and social), global health status, and cancer-related symptoms (e.g. fatigue, pain, nausea, and vomiting). The response format for each item is on a 4-point Likert scale ranging from1 (no) –to 4 (very much), except for items 29 and 30, which have a response format of 1-7. For each scale, a score ranging from 0 to 100 can be obtained, with higher scores indicating a better quality of life.

Caregiver-related outcomes

The 9-item Positive Aspects of Caregiving scale (PAC) (Lou et al., 2015; Tarlow et al., 2004) will be used to measure the psychosocial benefits of caregiving. It has good psychometric properties and consists of 9 items in total (e.g. makes me feel more useful). Each item is rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score on the PAC reflects a more positive perception of the caregiving experience.

The caregivers' health-related QoL will be measured using the Short Form-12 Health Status Questionnaire (SF-12) (Gandek et al., 1998), which is a reliable and valid tool. SF-12 consists of 12-items (e.g. he/she had to restrict certain types of work or other activities) that assess two different aspects of health: physical

health and mental health. Both aspects have a score ranging from 0 to 100, with higher scores indicating a higher physical or mental QoL.

Sample size

To ensure that this study can effectively investigate SC, a minimum of 500 patients and their caregivers (500 dyads) will be required. This number was determined according to previous research conducted in patients with chronic diseases, to achieve the necessary power to address all the goals of the study (Ausili et al., 2017; De Maria et al., 2019; Ercole Vellone, Maddalena De Maria, et al., 2020). In addition, a power analysis was performed to determine the minimum sample size required to address the second aim of this study (examine predictors of patient SC). A multiple linear regression will be conducted for this aim. Thus, to achieve a power of 0.80 and a significant level of $\alpha = 0.05$, considering a medium effect size based on Cohen f2 of 0.05 (Cohen, 1998) and 5 predictors (including comorbidity, self-efficacy, patient-centredness, and at least age and gender as sociodemographic predictors), the minimum sample size required would be 263 patients.

Data Analysis

Descriptive statistics (mean, median, frequencies) will be used to describe the sociodemographic and clinical characteristics of participants, as well as the SCOAAI and CC-SCOAAI scores. Subgroup descriptive analysis will be conducted to distinguish different levels of SC based on specific characteristics (e.g., gender, age, OAA used, etc).

To identify the predictors and outcomes of patient SC and CCSC, multiple linear regressions or logistic regressions will be performed. In addition, t-tests, analysis of variance (ANOVAs), simple regressions, multiple regressions, structural equation models, and generalised estimating equations will be performed to estimate the relationship between all patient, caregiver, and dyad factors associated with patient SC and CCSC. Finally, dyadic analyses will be performed to consider the patient-caregiver dyad, so to analyse the level of interrelation between variables of the patient and caregiver from a dyadic perspective. Data analysis will be carried out using Jasp® V. 0.98.0 (JASP Team, 2025), or R® software (R Core Team, 2025).

To account for the possibility of some patients/caregivers dropping out of the study and limit attrition bias, we will only include participants who took part at least in the initial data collection (T0) and the first follow-up at 3 months (T1). Should some participants drop out of the study at the subsequent follow-up at 6 months (T2) or only partially complete the questionnaires in one of the 3 phases, an analysis of the characteristics of the missing data will be carried out to determine the suitability of an imputation of these missing data using multiple imputation in order to reduce attrition bias (Asendorpf et al., 2014).

Ethical considerations

This study received approval from the Ethics Committee of the "Policlinico Tor Vergata" with reference number #188.22. . The study protocol was developed in accordance with the Good Clinical Practice Standards of the European Union and the Declaration of Helsinki. All participants will be asked to provide their informed consent in written form before they can join the study. They will be informed about the purpose of the study and assured that it does not involve any risks to them. The participants' information will be stored securely with access limited to researchers only. Participants will be identified by numerical codes in all phases of the study. The patient or caregiver can withdraw from the study at any time for any reason. If a participant cannot complete the study or wishes to discontinue participation, the reason for discontinuation will be recorded on the data collection form.

Discussion

This study will identify the different factors related to the patient, caregiver, and dyad that can influence the SC and CCSC in the context of patients with cancer receiving OAAs. Additionally, our study will determine whether the patient SC and CCSC can predict significant outcomes for both the patient, such as mortality, and the caregiver, such as their QoL. To our knowledge, this is the first study

of its kind to investigate SC and CCSC, with a focus on the dimensions of maintenance, monitoring, and management. The study also considers these dimensions in relation to their predictors and outcomes. The investigation will produce essential results that can guide clinical practice for patients treated with OAAs and their caregivers. Moreover, the study could produce evidence to guide future interventions aimed at improving SC and CCSC.

To date, various authors have studied SC and CCSC in different chronic diseases, such as heart failure (Cocchieri et al., 2015) and multiple chronic diseases (De Maria et al., 2022). Their studies have shown that SC and CCSC are crucial predictors of patient and caregiver quality of life (Iovino et al., 2021; Ercole Vellone, Valentina Biagioli, et al., 2020; Vellone, D'Agostino, et al., 2015). It is our belief that these predictors are also applicable to patients treated with OAAs. By measuring the three components of maintenance, monitoring, and management through SCOAAI and CC-SCOAAI, it could be possible to gain a better understanding of which components influence patient and caregiver outcomes.

Our study on SC differs from previous research by using a dyadic approach. As other studies have shown, patient SC and CCSC are interrelated, and patient variables can predict both patient SC and CCSC. In the same way, caregiver variables can predict CCSC and patient SC. Since patients and caregivers are interdependent, our dyadic analysis will allow us to control for this interdependence, leading to a more accurate understanding of the factors that influence each other.

Limitations

As this study will be conducted in a single European country, our results may be generalised with caution to other cultures. Another potential limitation may be related to longitudinal study design which may result in patients and caregivers dropping out. Finally, the convenience sampling approach used in this study is another potential limitation.

Conclusions

Recent advances in the field of oncology, among others, have led to an increased use of OAAs. Differently from cytotoxic anticancer agents, mainly delivered intravenously, OAAs are medicines taken at home under patient and/or caregiver surveillance. Therefore, although OAAs are better tolerated than cytotoxic anticancer agents, the patient and the caregiver must be well-educated to properly manage OAA assumption and their side effects. On the other hand, this "home scenario" highlights not only the importance of the caregiver's well-known role in managing patient disease and its complications but also a further new key role in the management of medicine(s) aimed at controlling cancer evolution. Therefore, knowing which SC behaviours should be implemented and how the caregiver reinforces patient SC behaviours is essential. The "Dyads-in-cancer" study could have significant implications for understanding how patients, caregivers, and dyads manage the SC process in the context of receiving OAAs. This study will also shed light on the factors that determine adequate levels of SC and identify the outcomes that can be improved through adequate SC behaviours. At a broader level, the "Dyads-in-cancer" study will contribute to expanding the knowledge about SC in cancer.

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Study Protocol

OPEN ACCESS

Self-Care Among Vulnerable Migrants Along Mediterranean and Western Balkan Migration Routes: Protocol for a Theory-Informed Mixed-Methods Systematic Review

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Abstract

Introduction. Vulnerable migrants may experience legal insecurity, socioeconomic precarity, disrupted social networks, language barriers, discrimination, and restricted or fragmented access to healthcare and social protection. Under these conditions, maintaining health may depend not only on formal healthcare but also on everyday actions undertaken to preserve health, recognize changes in health status, and respond to health problems. In this context, self-care, conceptualized within Riegel's Middle-Range Theory of Self-Care of Chronic Illness as a process of maintaining health with practices of health promotion, provides a relevant framework for examining these actions. According to this theory, self-care includes self-care maintenance, defined as daily behaviors to maintain health stability; self-care monitoring,

defined as actions aimed at monitoring one's physical and emotional conditions; and self-care management, defined as individual responses to changes in physical and emotional aspects. However, self-care is rarely examined explicitly as an overarching construct in migrant populations. Relevant health behaviors are often embedded within studies of health, illness, healthcare use, treatment adherence, coping, lifestyle behavior, healthcare utilization, or help-seeking. Consequently, self-care behaviors among vulnerable migrants and the contextual factors reported to influence them remain insufficiently synthesized within a common theoretical framework.

Objectives. The review has two objectives: (1) to identify and synthesize self-care behaviors reported among vulnerable migrants living in Europe and associated with Mediterranean and Western Balkan migration routes, and to classify these behaviors within self-care maintenance, monitoring, and management; and (2) to identify and synthesize contextual factors reported to influence these self-care behaviors.

Study Design. A mixed-methods systematic review using a convergent integrated approach in accordance with Joanna Briggs Institute methodology and a theory-informed synthesis based on Riegel's Middle-Range Theory of Self-Care.

Participants and setting. Studies involving first-generation adults aged ≥18 years who are vulnerable migrants residing in European host countries and whose migration circumstances are consistent with Mediterranean and/or Western Balkan migration pathways.

Intervention or Exposure. Migration-related and structural vulnerability.

Conclusions. The review will synthesize evidence on self-care behaviors among vulnerable migrants and the contextual factors reported to influence these behaviors. Their integration is expected to clarify both the health actions reported across heterogeneous health contexts and the conditions under which these actions are enabled, constrained, modified, interrupted, or supported, informing nursing and healthcare research, context-sensitive practice, and intervention development.

Keywords: Migrants, Migration Health, Self-Care, Structural Vulnerability, Mediterranean Migration Routes, Western Balkan Migration Routes

Introduction

International migration occurs under heterogeneous legal, political, socioeconomic, and health-related circumstances. For some individuals, migration takes place under conditions of conflict, persecution, forced displacement, economic insecurity, or irregular mobility (UNHCR, 2025). Vulnerability in migration contexts should not be considered an inherent characteristic of migrant status. Rather, it may arise from the interaction between individual circumstances and structural conditions, including legal insecurity, socioeconomic disadvantage, discrimination, unstable housing, disrupted social networks, and

barriers to health and social services (Caceres-Titos et al., 2025; Figura et al., 2024).

These conditions are particularly relevant along Mediterranean and Western Balkan migration routes toward and within Europe, where vulnerabilities may accumulate before departure, during transit, and after settlement. Post-migration circumstances, including restricted access to healthcare, social exclusion, discrimination, language barriers, legal uncertainty, and adverse living conditions, may further affect migrants' physical and psychosocial health after arrival in Europe (Figura et al., 2025; Stevenson et al., 2024). Under these circumstances, characterized by intersecting structural barriers and limited resources, maintaining health may depend not only on access to formal healthcare but also on the actions individuals undertake in everyday life to preserve their health, recognize changes in their condition, and respond to health problems.

Self-care provides a relevant conceptual perspective for examining these actions. Riegel and colleagues, in the Middle-Range Theory of Self-Care of Chronic Illness, conceptualize self-care as "a process of maintaining health through health-promoting practices and managing illness" (Riegel et al., 2012). This theory identifies three interrelated processes: self-care maintenance, defined as daily behaviors to maintain health stability; self-care monitoring, defined as actions aimed at monitoring one's physical and emotional conditions; and self-care management, defined as individual responses to changes in physical and emotional aspects. More recently, the theory was updated to reflect advances in the conceptualization of self-care and to include a broader range of individual and contextual factors that influence self-care (Riegel et al., 2026).

Evidence on self-care among migrant populations remains fragmented. Previous reviews have focused on specific populations, health conditions, or selected aspects of self-care, including: (1) cultural influences on self-care among African immigrants living with noncommunicable diseases; (2) mental health self-care among Arabic-speaking refugees and migrants; and (3) health literacy and self-care among immigrants with type 2 diabetes (Mehjabeen et al., 2023; Osokpo et al., 2021; Tørris & Nortvedt, 2024). More recently, Pratama et al. (2026) examined self-care needs among international migrants and travelers. However, to our knowledge, no review has synthesized self-care behaviors across different health contexts among vulnerable migrants using Riegel's Middle-Range Theory of Self-Care as a theory-informed framework, which may be useful for understanding how vulnerable migrants maintain their health, monitor changes in their condition, and respond to those changes.

In addition, self-care is not always explicitly identified as such in primary studies. Relevant behaviors may instead be embedded within broader studies of health, illness, healthcare use, or adaptation and reported under other constructs, including coping, treatment adherence, lifestyle behaviors, and help-seeking (Nyaaba et al., 2019; Teunissen et al., 2014). As a result, behaviors relevant to self-care may remain unrecognized. Using Riegel's Middle-Range Theory of Self-Care can help identify these behaviors even when they are described using different terminology, because the theory offers clear criteria for recognizing behaviors as part of the self-care process.

A further consideration is that self-care is also shaped by the conditions in which people live and manage their health. Among vulnerable migrants, these conditions may include knowledge and beliefs, family and social relationships, cultural and religious meanings, language and health literacy, access to healthcare, socioeconomic resources, legal conditions, and migration-related experiences (Kitson & Lawless, 2025; Riegel et al., 2012; Riegel et al., 2026). These factors may influence whether and how individuals maintain their health, monitor changes in their health, and respond to health problems. For example, knowing that a health behavior is recommended does not necessarily mean that it is performed, as adherence may be influenced by factors such as treatment side effects, social support, or everyday circumstances (Nyaaba et al., 2019). Similarly, restricted access to healthcare or limited knowledge of how to access services may influence whether and how vulnerable migrants seek care (Teunissen et al., 2014). Examining these influences is therefore necessary to understand both the self-care behaviors reported among vulnerable migrants and the conditions that influence them.

A theory-informed synthesis is therefore needed to synthesize self-care behaviors among vulnerable migrants and the contextual conditions that influence them. Riegel's Middle-Range Theory of Self-Care is particularly suitable

for this purpose because it provides a clear definition of self-care and its components, helps identify behaviors that may be described using different terminology, and recognizes the factors that influence self-care. This conceptualization is also relevant beyond illness management, as self-care occurs in both healthy and ill states (Riegel et al., 2012; Riegel et al., 2026). This framework may therefore support a more integrated understanding of how vulnerable migrants care for their health across different health contexts.

Objectives

The review has two objectives: (1) to identify and synthesize self-care behaviors reported among vulnerable migrants living in Europe and associated with Mediterranean and Western Balkan migration routes, and to classify these behaviors within self-care maintenance, monitoring, and management; and (2) to identify and synthesize contextual factors reported to influence these self-care behaviors.

Methods

Study design

The two review questions for the planned systematic review will be the following: (1) Which self-care behaviors are reported among vulnerable migrants associated with Mediterranean and Western Balkan migration routes, and how can these behaviors be classified within self-care maintenance, monitoring, and management? and (2) Which contextual factors are reported to influence these self-care behaviors?

This study will be conducted as a mixed-methods systematic review using a convergent integrated approach in accordance with JBI methodology for mixed-methods evidence synthesis (Aromataris et al., 2024). This design was selected because both qualitative and quantitative evidence can contribute to answering the same review questions.

The review will include two analytical components. The behavioral component will identify and synthesize self-care behaviors, while the contextual component will identify and synthesize factors reported to influence these behaviors. The two components will initially be analyzed separately and subsequently integrated. In both analytical components, quantitative findings will be transformed into textual statements and analyzed together with qualitative findings (Stern et al., 2021).

The synthesis will be informed by Riegel's Middle-Range Theory of Self-Care (Riegel et al., 2012). Behavioral evidence will first be analyzed inductively by grouping self-care behaviors into behavioral patterns and broader conceptual categories. These categories and patterns will then be classified within self-care maintenance, monitoring, and management using Riegel's Middle-Range Theory of Self-Care. Contextual evidence will be analyzed separately to identify recurring factors reported to influence self-care behaviors. Explicitly reported relationships between contextual factors and self-care behaviors or processes will then be integrated with the behavioral findings.

The protocol is reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement (Moher et al., 2015; Shamseer et al., 2015). The completed systematic review will be reported according to PRISMA 2020 (Page et al., 2021).

The review was prospectively registered in PROSPERO (CRD420250388984).

Eligibility criteria

Studies will be eligible if they include first-generation vulnerable migrants aged 18 years or older residing in European host countries, irrespective of health status, and originating from North Africa, the Middle East, South Asia, or other migration contexts associated with Mediterranean and/or Western Balkan routes. Eligibility will focus on populations experiencing migration-related or structural vulnerability, including refugees, asylum seekers, undocumented migrants, migrants experiencing legal or socioeconomic precarity, and other first-generation migrant groups exposed to vulnerability during migration or settlement.

In line with the aim of the review, studies will be eligible when they report actions performed by participants that are consistent with self-care maintenance, monitoring, or management, regardless of the terminology used in the original study. Behaviors described under constructs

such as adherence, coping, help-seeking, or lifestyle practices will therefore be eligible when the reported action falls within the conceptual scope of self-care maintenance, monitoring, or management.

Eligibility will not depend on a specific diagnosis or health condition. Studies conducted in chronic, acute, episodic, reproductive, psychological, preventive, or health-promotion contexts, as well as studies involving populations without a reported diagnosis, may be included when they report behaviors meeting the conceptual criteria for self-care. Contextual factors reported to influence these behaviors will also contribute to data extraction and synthesis.

Studies including both eligible and ineligible populations will be considered when findings concerning the eligible population are reported separately or can be clearly disaggregated. No minimum proportion of eligible participants will be required. Only findings attributable to the eligible population will contribute to data extraction and synthesis.

Secondary reviews, protocols, editorials, commentaries, theoretical papers without primary empirical data, conference abstracts without sufficient full-text information, and unpublished materials will be excluded. No restrictions will be imposed by publication year or language.

Information sources and search strategy

Systematic searches will be conducted in PubMed, Scopus, Web of Science Core Collection and, through EBSCOhost, CINAHL, APA PsycArticles, APA PsycInfo, and Psychology and Behavioral Sciences Collection. Databases will be searched from inception.

The search strategies were developed using controlled vocabulary, where available, together with free-text terms related to migration, self-care, and the European/Mediterranean context. The PubMed strategy served as the reference strategy and was adapted to the indexing systems, syntax, field structures, and search functionality of the other databases. Complete database-specific search strategies are presented in Supplementary File 1.

The self-care component was designed to be broad to maximize sensitivity for potentially relevant health behaviors that may be reported using other terminology.

Study selection

Search results will be exported to EndNote for reference management and duplicate removal and subsequently imported into Rayyan (Ouzzani et al., 2016).

Two reviewers will independently screen titles and abstracts against predefined eligibility criteria. A record will progress to full-text assessment whenever either reviewer considers it potentially eligible.

Potentially eligible full texts will subsequently be assessed independently by two reviewers. A primary reason for exclusion will be documented for studies excluded at full-text assessment.

Disagreements will initially be resolved through discussion and consensus. When consensus cannot be reached, an additional reviewer will be consulted. When uncertainty specifically concerns the conceptual interpretation of self-care or whether a potentially relevant behavior falls within the conceptual scope of self-care, a member of the research team with extensive expertise in self-care theory will be consulted.

The complete study selection process will be documented using a PRISMA 2020 flow diagram (Page et al., 2021).

Data extraction and initial analysis

Data will be extracted independently by two reviewers using standardized forms developed for the review. The two extractions will be compared, and disagreements will be resolved through discussion and consensus. A third reviewer will then check the extracted data to verify completeness and accuracy. A member of the research team with expertise in self-care theory will be consulted when there is uncertainty about whether a reported action represents self-care or about its classification. The same expert will also review the final behavioral classifications for consistency with Riegel's Middle-Range Theory of Self-Care.

For each included study, reviewers will first record the main study characteristics, including authorship and publication year, study aim, host country and setting, study design and methodological approach, data-collection

methods, total sample and review-eligible sample, participants' country or region of origin, migrant or protection status where available, duration of residence, age, sex/gender, health condition or topic, principal findings, methodological limitations, and relevant extraction notes.

For the extraction of self-care behaviors, a dedicated table will be used containing the following fields: evidence in the text, self-care behavior, behavioral pattern, conceptual category, and self-care dimension. First, reviewers will examine the findings of each study to identify self-care behaviors. When a finding meets the review criteria, reviewers will record the exact evidence reported in the primary study. For qualitative findings, this may include a participant quotation and/or the authors' description of the finding. For quantitative findings, reviewers will record the relevant numerical result. Reviewers will then formulate a self-care behavior, defined as a clear and concise statement describing the action represented by the extracted evidence. For qualitative findings, this statement will summarize the action described in the source text. For quantitative findings, this step will involve qualitization, whereby the numerical finding will be transformed into a textual statement describing the behavior while preserving the meaning of the original result (Stern et al., 2021). Self-care behaviors describing the same or closely related actions and purposes will then be grouped into behavioral patterns. A behavioral pattern will represent a group of self-care behaviors that share similar actions and purposes. Behavioral patterns that are conceptually related will subsequently be grouped into broader conceptual categories. A conceptual category will represent a higher-order grouping of behavioral patterns that are conceptually related. Finally, the conceptual categories (and their behavioral patterns) will be classified within self-care maintenance, monitoring, or management according to the function of the behaviors they contain, using Riegel's Middle-Range Theory of Self-Care.

Contextual evidence will be extracted separately. A contextual factor will be defined as any condition, resource, relationship, experience, or individual or structural characteristic reported to influence self-care behaviors. For the extraction of contextual factors, a dedicated table will be used containing the following fields: evidence in the text, contextual factor, contextual pattern, conceptual category, and relationship with the self-care dimension (maintenance, monitoring, or management). For each contextual finding, reviewers will record the contextual factor, the study reference, the supporting evidence, and any explicitly reported relationship with a specific self-care behavior or process. For quantitative findings, the numerical result will be qualitized into a textual statement describing the reported influence, while the original numerical evidence will be retained. Contextual factors describing the same or closely related influences will then be grouped into contextual patterns. A contextual pattern will represent a group of contextual factors that share similar influences on self-care. Contextual patterns that are conceptually related will subsequently be grouped into broader conceptual categories (Figure 1).

Methodological quality assessment

Methodological quality will be assessed independently by two reviewers using the JBI Critical Appraisal Checklist appropriate to the evidence contributed by each study (Aromataris et al., 2024).

Disagreements will be resolved through discussion and consensus. If agreement cannot be reached, an additional reviewer will be consulted.

The appraisal results will be summarized descriptively. No percentage cut-off will be used to determine study eligibility, and no study will be excluded solely because of its methodological quality. Instead, methodological quality will be considered when interpreting the findings contributed by each study and the behavioral or contextual patterns developed from those findings.

Data synthesis

Data synthesis will follow a convergent integrated, theory-informed approach in accordance with JBI methodology for mixed-methods evidence synthesis (Aromataris et al., 2024; Stern et al., 2021).

Findings will be presented through a narrative synthesis (Popay et al., 2006), supported, where appropriate, by tables summarizing the behavioral, contextual, and integrated findings.

For the first review question, self-care

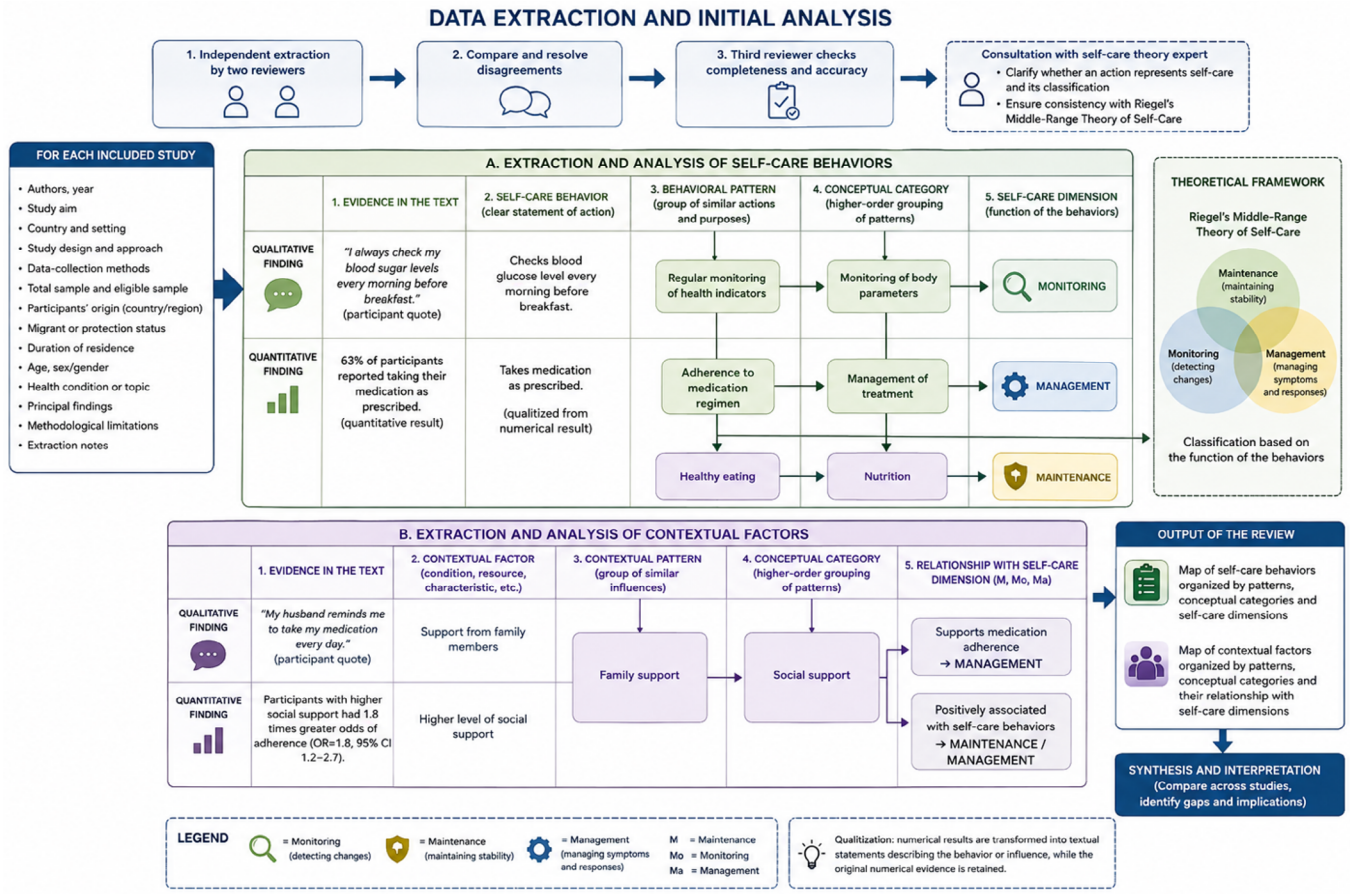


Figure 1. Data extraction and initial analytical process. Example of schematic representation of the extraction and organization of self-care behaviors and contextual factors.

behaviors will be synthesized separately within self-care maintenance, monitoring, and management. For each domain, the conceptual categories identified will be presented. Within each conceptual category, the behavioral patterns will be reported, together with the self-care behaviors included in each pattern and the studies contributing evidence.

For the second review question, contextual factors will be synthesized separately using the contextual patterns and conceptual categories. For each conceptual category, the contextual patterns will be presented together with the contextual factors included in each pattern and the studies contributing evidence. Any explicitly reported relationship between a contextual factor and a specific self-care behavior or process will be preserved in the synthesis.

The behavioral and contextual syntheses will then be integrated. When a primary study explicitly reports a relationship between a contextual factor and a self-care behavior or process, this relationship will be retained and interpreted at the level supported by the original evidence. Contextual factors without an explicitly reported relationship with a specific behavior or self-care process will remain part of the broader contextual synthesis and will not be assigned to a specific behavior or self-care domain.

Ethical considerations

Ethics approval is not required because this systematic review uses data reported in previously published primary studies and does not involve collection of new participant-level data.

Discussion

This review is expected to provide a structured understanding of self-care among vulnerable migrants living in Europe and associated with Mediterranean and Western Balkan migration

routes. Its main contribution will be to bring together behaviors that are often reported across different health topics and under different terms, and to interpret them within a common self-care framework. By organizing findings within self-care maintenance, monitoring, and management, the review may clarify how vulnerable migrants maintain health, recognize changes in their condition, and respond when health problems or treatment-related issues arise.

A further contribution will be the identification of contextual factors reported to influence these behaviors. Self-care does not occur in isolation, and the same action may be supported or constrained by social, cultural, economic, legal, and healthcare-related conditions. Examining these factors alongside behavioral findings may help explain why some self-care practices are adopted, modified, delayed, or not performed. This is particularly relevant for vulnerable migrant populations, whose ability to care for their health may be affected by unstable living conditions, limited access to healthcare, language barriers, legal uncertainty, disrupted social networks, and other migration-related circumstances. The review may therefore provide a more complete understanding of self-care by considering both what people do and the conditions in which these behaviors occur.

The use of Riegel's Middle-Range Theory of Self-Care is also expected to provide a clear structure for distinguishing maintenance, monitoring, and management while allowing behaviors to be interpreted according to their purpose and context. This is especially important when primary studies do not explicitly use the term self-care. A theory-informed synthesis may therefore reveal relevant behaviors that would remain fragmented if they were considered only within the terminology used by individual studies.

The findings may have implications for nursing practice, research, and service organization. For nurses and other healthcare professionals, identifying common self-care behaviors and the factors that influence them may support more appropriate assessment, education, and self-care support for vulnerable migrants. For researchers, the review may help clarify how self-care is currently described and measured in migrant populations and identify areas that remain underexplored. At the service level, understanding contextual influences may help identify conditions that facilitate or hinder self-care and inform the development of more accessible and responsive healthcare interventions.

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Supplementary File 1. Search strings.

PubMed	
1	"Self-Management"[MeSH Terms] OR "Self Care"[MeSH Terms] OR "Health Behavior"[MeSH Terms] OR "Self Efficacy"[MeSH Terms] OR "Health Promotion"[MeSH Terms] OR "Healthy Lifestyle"[Mesh Terms] OR "self-management"[Title/Abstract] OR "self management"[Title/Abstract] OR "self-manag"[Title/Abstract] OR "self manag"[Title/Abstract] OR "self-managable"[Title/Abstract] OR "self managable"[Title/Abstract] OR "self-manage*"[Title/Abstract] OR "self manage*"[Title/Abstract] OR "self-manageable"[Title/Abstract] OR "self manageable"[Title/Abstract] OR "self-managed"[Title/Abstract] OR "self managed"[Title/Abstract] OR "self-manager*"[Title/Abstract] OR "self manager*"[Title/Abstract] OR "self-managerial"[Title/Abstract] OR "self managerial"[Title/Abstract] OR "self-managing"[Title/Abstract] OR "self managing"[Title/Abstract] OR "symptom* management"[Title/Abstract] OR "symptom* response"[Title/Abstract] OR "self care"[Title/Abstract] OR "self monitor*"[Title/Abstract] OR "self-monitor*"[Title/Abstract] OR "self monitorable"[Title/Abstract] OR "self-monitorable"[Title/Abstract] OR "self monitored"[Title/Abstract] OR "self-monitored"[Title/Abstract] OR "self monitoring"[Title/Abstract] OR "self-monitoring"[Title/Abstract] OR "self monitoring"[Title/Abstract] OR "self-monitoring"[Title/Abstract] OR "monitor symptom*"[Title/Abstract] OR "monitor health status"[Title/Abstract] OR "self-care"[Title/Abstract] OR "self caring"[Title/Abstract] OR "self-caring"[Title/Abstract] OR "self efficacy"[Title/Abstract] OR "self-efficacy"[Title/Abstract] OR "self-agency"[Title/Abstract] OR "self-help"[Title/Abstract] OR "self-administration"[Title/Abstract] OR "self administration"[Title/Abstract] OR "self-medication"[Title/Abstract] OR "self medication*"[Title/Abstract] OR "self-treatment*"[Title/Abstract] OR "self treatment*"[Title/Abstract] OR "self-maintenance"[Title/Abstract] OR "self maintenance"[Title/Abstract] OR "health behavior*"[Title/Abstract] OR "health behaviour*"[Title/Abstract] OR "self-care behaviour*"[Title/Abstract] OR "self care behaviour*"[Title/Abstract] OR "health promotion*"[Title/Abstract] OR "health prevention"[Title/Abstract] OR "healthy lifestyle*"[Title/Abstract] OR "healthy life style*" OR "lifestyle change"[Title/Abstract]
2	"Transients and Migrants"[MeSH Terms] OR Refugees [MeSH Terms] OR "Undocumented Immigrants"[MeSH Terms] OR "transients and migrants"[Title/Abstract] OR refugee*[Title/Abstract] OR "asylum seeker*"[Title/Abstract] OR "asylum-seeker*"[Title/Abstract] OR "displaced person*"[Title/Abstract] OR "displaced people"[Title/Abstract] OR "undocumented immigrant*"[Title/Abstract] OR immigrant*[Title/Abstract] OR migrant*[Title/Abstract] OR "newly arrived" [Title/Abstract] OR stateless[Title/Abstract] OR "forced migrant*"[Title/Abstract] OR "vulnerable migrant*"[Title/Abstract]
3	"Mediterranean Region"[MeSH Terms] OR "Mediterranean Region" [Title/Abstract] OR "Mediterranean Sea"[Title/Abstract] OR "Mediterranean"[Title/Abstract] OR Europe[Title/Abstract] OR Germany[Title/Abstract] OR "United Kingdom"[Title/Abstract] OR France[Title/Abstract] OR Italy[Title/Abstract] OR Spain[Title/Abstract] OR Ukraine[Title/Abstract] OR Poland[Title/Abstract] OR Romania[Title/Abstract] OR Netherlands[Title/Abstract] OR Belgium[Title/Abstract] OR "Czech Republic"[Title/Abstract] OR Czechia[Title/Abstract] OR Greece[Title/Abstract] OR Portugal[Title/Abstract] OR Sweden[Title/Abstract] OR Hungary[Title/Abstract] OR Belarus[Title/Abstract] OR Austria[Title/Abstract] OR Serbia[Title/Abstract] OR Switzerland[Title/Abstract] OR Bulgaria[Title/Abstract] OR Denmark[Title/Abstract] OR Finland[Title/Abstract] OR Slovakia[Title/Abstract] OR Norway[Title/Abstract] OR Ireland[Title/Abstract] OR Croatia[Title/Abstract] OR Moldova[Title/Abstract] OR Bosnia[Title/Abstract] OR Herzegovina[Title/Abstract] OR Albania[Title/Abstract] OR Lithuania[Title/Abstract] OR "North Macedonia"[Title/Abstract] OR Slovenia[Title/Abstract] OR Latvia[Title/Abstract] OR Estonia[Title/Abstract] OR Montenegro[Title/Abstract] OR Luxembourg[Title/Abstract] OR Malta[Title/Abstract] OR Iceland[Title/Abstract] OR Andorra[Title/Abstract] OR Monaco[Title/Abstract] OR Liechtenstein[Title/Abstract] OR "San Marino"[Title/Abstract] OR "Holy See"[Title/Abstract]
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Scopus	
1	TITLE-ABS-KEY("self-management" OR "self management" OR "self-manag" OR "self manag" OR "self-managable" OR "self managable" OR "self-manage*" OR "self manage*" OR "self-manageable" OR "self manageable" OR "self-managed" OR "self managed" OR "self-manager*" OR "self manager*" OR "self-managerial" OR "self managerial" OR "self-managing" OR "self managing" OR "symptom* management" OR "symptom* response" OR "self care" OR "self monitor*" OR "self-monitor*" OR "self monitorable" OR "self-monitorable" OR "self monitored" OR "self-monitored" OR "self monitoring" OR "self-monitoring" OR "self monitoring" OR "self-monitoring" OR "monitor symptom*" OR "monitor health status" OR "self-care" OR "self caring" OR "self-caring" OR "self efficacy" OR "self-efficacy" OR "self-agency" OR "self-help" OR "self-administration" OR "self administration" OR "self-medication" OR "self medication*" OR "self-treatment*" OR "self treatment*" OR "self-maintenance" OR "self maintenance" OR "health behavior*" OR "health behaviour*" OR "self-care behaviour*" OR "self care behaviour*" OR "health promotion*" OR "health prevention" OR "healthy lifestyle*" OR "healthy life style*" OR "lifestyle change")
2	TITLE-ABS-KEY("transients and migrants" OR refugee* OR "asylum seeker*" OR "asylum-seeker*" OR "displaced person*" OR "displaced people" OR "undocumented immigrant*" OR immigrant* OR migrant* OR "newly arrived" OR stateless OR "forced migrant*" OR "vulnerable migrant*")
3	TITLE-ABS-KEY("Mediterranean Region" OR "Mediterranean Sea" OR "Mediterranean" OR Europe OR Germany OR "United Kingdom" OR France OR Italy OR Spain OR Ukraine OR Poland OR Romania OR Netherlands OR Belgium OR "Czech Republic" OR Czechia OR Greece OR Portugal OR Sweden OR Hungary OR Belarus OR Austria OR Serbia OR Switzerland OR Bulgaria OR Denmark OR Finland OR Slovakia OR Norway OR Ireland OR Croatia OR Moldova OR Bosnia OR Herzegovina OR Albania OR Lithuania OR "North Macedonia" OR Slovenia OR Latvia OR Estonia OR Montenegro OR Luxembourg OR Malta OR Iceland OR Andorra OR Monaco OR Liechtenstein OR "San Marino" OR "Holy See")

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1	AB(“self-management” OR “self management” OR “self-manag” OR “self manag” OR “self-managable" OR “self managable" OR “self-manage*” OR “self manage*” OR “self-manageable” OR “self manageable” OR “self-managed” OR “self managed” OR “self-manager*” OR “self manager*” OR “self-managerial” OR “self managerial” OR “self-managing” OR “self managing” OR "symptom* management" OR "symptom* response" OR "self care" OR “self monitor*” OR “self-monitor*” OR “self monitorable” OR “self-monitorable” OR “self monitored” OR “self-monitored” OR “self monitoring” OR “self-monitoring” OR "self monitoring" OR "self-monitoring" OR "monitor symptom*" OR "monitor health status" OR "self-care" OR “self caring” OR “self-caring” OR "self efficacy" OR "self-efficacy" OR "self-agency" OR "self-help" OR “self-administration” OR “self administration” OR “self-medication” OR "self medication*" OR “self-treatment*” OR "self treatment*" OR "self-maintenance" OR "self maintenance" OR “health behavior*” OR "health behaviour*" OR "self-care behaviour*" OR "self care behaviour*" OR “health promotion*” OR "health prevention" OR "healthy lifestyle*" OR “healthy life style*” OR "lifestyle change")
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3	AB (“Mediterranean Region” OR “Mediterranean Sea” OR “Mediterranean” OR Europe OR Germany OR "United Kingdom" OR France OR Italy OR Spain OR Ukraine OR Poland OR Romania OR Netherlands OR Belgium OR "Czech Republic" OR Czechia OR Greece OR Portugal OR Sweden OR Hungary OR Belarus OR Austria OR Serbia OR Switzerland OR Bulgaria OR Denmark OR Finland OR Slovakia OR Norway OR Ireland OR Croatia OR Moldova OR Bosnia OR Herzegovina OR Albania OR Lithuania OR "North Macedonia" OR Slovenia OR Latvia OR Estonia OR Montenegro OR Luxembourg OR Malta OR Iceland OR Andorra OR Monaco OR Liechtenstein OR "San Marino" OR "Holy See")
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Original Research

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Understanding Clinical Teaching in Midwifery Education: Validation of the MidPaACT Tool in the Italian Context

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Abstract

Introduction. Midwifery education integrates theoretical instruction with clinical practice, in which supervisory relationships are pivotal. The quality of mentorship substantially influences students' competence, confidence, and professional identity, and is largely determined by midwives' awareness of their role as preceptors and how this is enacted in practice. This study aims to provide a valid instrument for evaluating clinical teaching in midwifery education by translating, culturally adapting, and psychometrically validating the Midwifery Perceptions and Assessment of Clinical Teaching (MidPaACT) tool in the Italian context.

Methods. The MidPaACT questionnaire was translated and culturally adapted following established international guidelines. The process included forward translation, synthesis, back translation, expert panel review, and pilot testing. Data were collected through an online survey completed by preceptor midwives involved in undergraduate midwifery education. Construct validity was assessed using confirmatory factor analysis using a Diagonally Weighted Least Squares estimator. Model fit was evaluated using RMSEA, SRMR, CFI,

and TLI indices. Internal consistency reliability was assessed using Cronbach's alpha coefficients.
Results. A total of 168 preceptor midwives participated. Confirmatory factor analysis supported the original two-factor structure ('Supporting students to learn' and 'Safety in learning') and indicated acceptable model fit (RMSEA = 0.08; SRMR = 0.105; CFI = 0.973; TLI = 0.971). Internal consistency was satisfactory for both subscales (α = 0.88 and α = 0.77). Participants reported high levels of engagement in supporting student learning and ensuring safety in clinical practice, while highlighting areas for improvement in academic–clinical collaboration and culturally responsive supervision.
Discussion. The Italian version of the MidPaACT demonstrates satisfactory psychometric properties and provides a valid tool for the systematic evaluation of clinical teaching in midwifery education. Its use can support the development of targeted faculty development initiatives and strengthen evidence-informed approaches to improving the quality of clinical education.

Keywords: Midwifery, Nurse Midwives, Clinical Teaching, Preceptorship, Midwifery Education, Clinical Education

Introduction

Midwifery education integrates theoretical instruction with extensive clinical training, both of which are essential for the development of professional competence (McKellar & Kempster, 2017). Although the organisation and relative balance of these components vary across countries – and even within the same national context – the centrality of clinical practice remains constant. Clinical placements are the settings in which students consolidate knowledge, refine technical skills, and develop professional identity. In this complex learning environment, students are supported by a preceptor midwife who provides guidance, supervision, and formative feedback throughout the learning process. The quality of this support is therefore central to students' learning experiences and outcomes.

The student-preceptor relationship is widely recognised as one of the most influential determinants of the quality of clinical learning (Hughes & Fraser, 2011). Evidence suggests that this relationship can either facilitate or hinder students' professional growth. A supportive and collaborative mentoring relationship promotes confidence, strengthens self-esteem, and fosters the development of both clinical competence and professional identity (Sheehan et al., 2022; Mauri et al., 2020). Accordingly, the preceptor is recognised as playing an important role not only in supporting skill acquisition but also in shaping students' professional identity and values. However, the literature also identifies the supervisory relationship as a potential source of fear and anxiety among midwifery students, profoundly shaping their emotional experience of clinical education and significantly influencing their aspirations as future midwives (Neri et al., 2026).

High-quality clinical learning depends on excellence in supervisory relationships, access to diverse and level-appropriate learning opportunities, effective communication, and a workplace culture committed to best practice and continuous learning (Griffiths et al., 2023). However, fulfilling the preceptor role requires more than clinical expertise alone. Midwives are often appointed as mentors based on availability rather than preparedness, and their perceptions of readiness, role clarity, and educational competence remain underexplored (Griffiths et al., 2021). A systematic review highlighted the scarcity of profession-specific instruments capable of capturing midwife preceptors' perceptions of their role and identifying their

educational needs (Griffiths et al., 2021). This gap is particularly relevant in midwifery, where professional philosophy, relational continuity, and woman-centred care are integral to both practice and education.

In 2020, Griffith et al. developed the Midwifery Student Evaluation of Practice (MidSTEP) tool to measure students' perceptions of their clinical learning experiences (Griffiths et al., 2020). The MidSTEP tool was linguistically and culturally validated in Italy in 2024 (Nespoli et al., 2024), and demonstrated good psychometric properties, which enabled the systematic evaluation of clinical learning environments within Italian midwifery programmes. Building on this work, a multicentre Italian study is currently underway to investigate the quality of clinical placements from the students' perspective.

To address the need for evaluating clinical placements from multiple perspectives, Griffiths et al. (2023) developed the Midwifery Perceptions and Assessment of Clinical Teaching (MidPaACT) tool. This instrument was specifically designed to assess midwife preceptors' perceptions of their role in supporting student learning in clinical settings. Through the provision of a profession-specific, psychometrically tested tool, the MidPaACT addresses a significant gap in the literature and captures key dimensions of clinical teaching, including supporting student learning and ensuring safety in practice.

The present study aims to conduct the linguistic and cultural validation of the MidPaACT tool in the Italian context. This work represents a necessary step toward completing a broader research agenda that comprehensively analyses the quality of clinical placements in Italian midwifery degree programmes, integrating both students' and preceptors' perspectives. By enabling an appropriate assessment of preceptors' perceptions, this study seeks to contribute to the optimisation of clinical education and the strengthening of midwifery training at both institutional and national levels.

Methods

Study Design

This was a cross-cultural adaptation and psychometric validation study within the Italian context. The study was conducted in two phases: 1) development of the Italian version through translation and assessment of semantic, cultural, and content equivalence (Wild et al. 2005), followed by 2) validation of the instrument through data collection and analysis to ascertain the psychometric properties of the Italian MidPaACT version (I-MidPaACT). In addition, measurement properties were assessed according to the psychometric validation standards established by the COSMIN initiative for health measurement instruments (Mokkink et al., 2010).

Description of the MidPaACT questionnaire

The MidPaACT questionnaire, developed by Griffiths et al. (2023), assesses midwives' perceptions of their role in preceptoring midwifery students in clinical practice. It consists of 24 items rated on a 5-point Likert scale (1 = "Never" to 5 = "Always"), grouped into two domains: Supporting students to learn (15 items) and Safety in learning (9 items). Higher scores indicate stronger perceptions of midwives' role in supporting students' clinical learning.

The total score is calculated by summing the responses to all 24 items. No reverse-coded items are included in the instrument. Accordingly, the total possible score ranges from 24 to 120, while subscale scores are obtained by summing the items belonging to each respective domain.

In the original validation study, the MidPaACT demonstrated good psychometric properties, with high internal consistency (Cronbach's alpha = 0.89; subscales $\alpha > 0.70$) and support for the two-factor structure through factor analysis. These findings support its use for assessing midwives' perceptions of their educational role and justify its adaptation into the Italian context.

Translation and Cross-Cultural Adaptation of the MidPaACT

With permission from the developers, the MidPaACT was translated and culturally adapted into Italian following the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (Wild et al., 2005).

The process included: (1) two independent forward translations into Italian by bilingual translators with midwifery expertise; (2) synthesis of the forward translations by an

independent native Italian speaker; (3) two independent back-translations into English by bilingual translators blinded to the original instrument; (4) comparison of back-translations with the original to ensure semantic, conceptual, and experiential equivalence.

An expert committee of five experienced Italian midwives reviewed all versions, resolving discrepancies through consensus and ensuring semantic, idiomatic, experiential, and conceptual equivalence. The pre-final Italian version was then pilot-tested on a small sample of midwives (n = 7) to assess clarity, comprehension, and cultural relevance. Minor adjustments were made based on feedback, resulting in the final Italian MidPaACT (I-MidPaACT).

Setting and Participants

Eligible participants were preceptor midwives affiliated with the University of Parma, Bicocca University of Milan, the University of Milan, and Saint Camillus International University of Rome (UniCamillus). Inclusion criteria included being a midwife preceptor in hospital or local services for students enrolled in the Midwifery degree courses involved in the validation study.

An invitation email was sent to all eligible midwives through institutional mailing lists. The email included a Participant Information Sheet detailing the study objectives, procedures, the voluntary nature of participation, and data confidentiality. Potential participants were given adequate time to consider participation before accessing the survey.

Midwives who agreed to participate completed the questionnaire anonymously via an online platform (Google Forms). A member of the research team was available to answer questions, provide additional information, and clarify any aspects of the study. Data were collected between December 2025 and January 2026.

To ensure an adequate sample size for psychometric evaluation, the study followed recommendations for instrument validation (Beaton et al., 2000): at least 10 participants per item of the largest subscale (Supporting students to learn, 15 items), resulting in a minimum target sample of 150 participants.

Statistical Analysis

Descriptive statistics were used to summarise participants' sociodemographic and professional characteristics and MidPaACT distributions. Surveys with more than 10 % of missing responses were discarded. Psychometric analyses were conducted in accordance with COSMIN methodology for evaluating the measurement properties of health-related instruments (Mokkink et al., 2010). The construct validity of the I-MidPaACT was evaluated using confirmatory factor analysis (CFA) to test the original factorial structure proposed by the authors (Griffiths et al., 2023) within the Italian context. Given the ordinal nature of the Likert-type items, the CFA was conducted using a Diagonally Weighted Least Squares (DWLS) estimator. Model fit was evaluated using absolute and incremental fit indices. Absolute fit was assessed using the Root Mean Square Error of Approximation (RMSEA), and the Standardized Root Mean Square Residual (SRMR), with values <0.08 and <0.05 indicating acceptable model fit, respectively. Incremental fit was evaluated using the Comparative Fit Index (CFI) and the Tucker-Lewis Index (TLI), with values >0.90 considered indicative of good fit (Dash & Paul, 2021). Internal consistency reliability was assessed for each I-MidPaACT subscale using Cronbach's alpha coefficient.

All statistical analyses were conducted using R software (version 4.3.2).

Ethical Consideration

The study was approved by the Local Ethics Committee of UniCamillus (reference number: E00430-2025). All procedures were conducted in accordance with the principles of the Declaration of Helsinki and relevant national regulations.

Participation was voluntary, and all eligible midwives received detailed information regarding the study aims, procedures, confidentiality, and the right to withdraw at any time without consequence. Written informed consent was obtained from each participant prior to participation.

All data were collected anonymously and handled in accordance with applicable data protection regulations. No personally identifiable information was recorded, and data were stored securely with access restricted to the research team.

Results

Description of the sample characteristics

A total of 168 preceptors participated in the study. Most participants were employed in hospital settings (88.7%, n = 149) and were mainly located in Lombardy (58.3%), Emilia Romagna (20.8%), and Lazio (19.6%). Regarding professional experience, 65% of participants had more than 10 years of clinical experience, although 41% reported less than 6 years of experience as preceptors. Only 35.1% had received formal preceptor-specific education. Among participants, 30% held a master's degree and 25% had completed a first or second level master's programme. Detailed sample characteristics are reported in Table 1.

Table 1. Sociodemographic and professional characteristics of participating midwife preceptors.

		n	%
Age of participants (years)	<26	9	5.36
	26-35	56	33.33
	36-45	57	33.93
	46-55	29	17.26
	>55	17	10.12
Highest educational qualification	Bachelor degree	73	43.45
	Master's degree	50	29.76
	First-level master's degree	39	23.21
	Second-level master's degree	5	2.98
	PhD	1	0.60
Years of professional experience	<6	28	16.67
	6-10	31	18.45
	11-20	57	33.93
	>20	52	30.95
Clinical setting	Hospital setting	149	88.69
	Community setting	19	11.31
Region of work	Veneto	2	1.20
	Lombardy	98	58.34
	Emilia Romagna	35	20.82
	Lazio	33	19.64
Years of experience as Preceptor	<6	70	41.67
	6-10	45	26.79
	11-20	38	22.62
	>20	15	8.93
Previous preceptor education	No	109	64.88
	Yes	59	35.12

Psychometric characteristics of I-MidPaACT

The CFA of the original MidPaACT structure, using the DWLS estimator, was performed to assess the structural validity of the Italian version of the instrument. Model parameter estimates (Figure 1) and fit indices indicated an overall acceptable fit for of the model, despite variability across indices: RMSEA = 0.08, SRMR = 0.105, CFI = 0.973, and TLI = 0.971. Overall, the fit indices broadly supported the original two-factor structure of the MidPaACT, consistent with previous studies (Griffiths et al., 2023), although the SRMR exceeded conventional thresholds. The two-factor model explained an average of 48.77% of the variance of the observed variables.

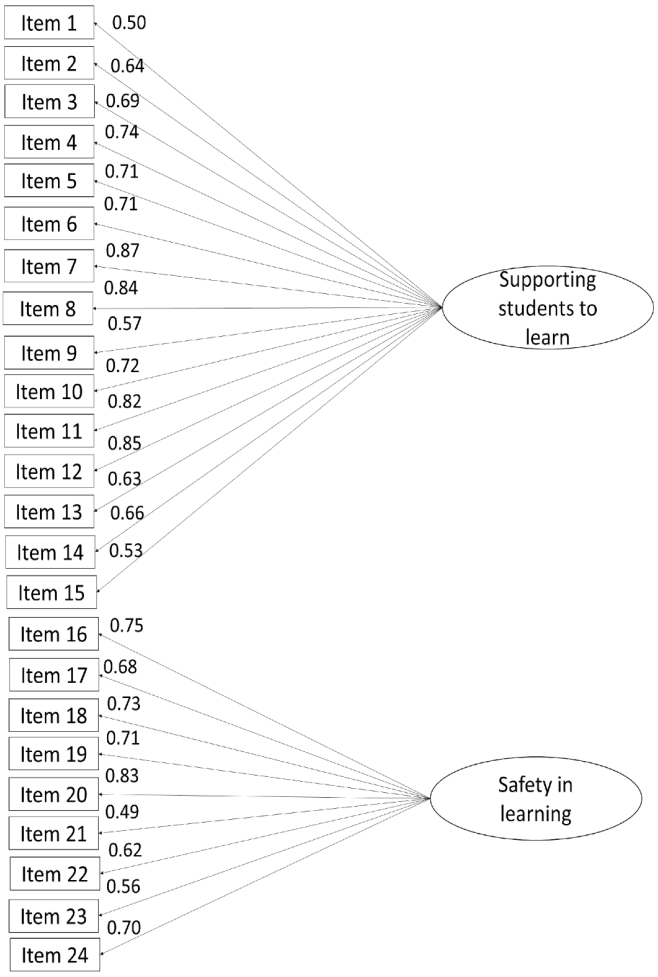


Figure 1. Factor structure of I-MidPaACT computed from Confirmatory Structural Analysis.

Internal consistency reliability was satisfactory for both subscales, with Cronbach's alpha values of 0.88 for Supporting students to learn and 0.77 for Safety in learning.

Midwives' Perceptions and Assessment of Clinical Teaching (MidPaACT) tool scores

The overall mean score of the MidPaACT tool was 105.1 (SD = 9.4), corresponding to an average item score of 4.38 (SD = 0.80). Distribution of responses for each item, including item mean scores and standard deviations, is reported in Table 2. These findings indicate that participants generally perceived themselves as offering substantial and consistent support to students during clinical practice.

Table 2. Distribution of responses on each item, item mean score, and standard deviation (SD).

	Never (1)		Seldom (2)		Sometimes (3)		Usually (4)		Always (5)		Item mean score (SD)
	n	%	n	%	n	%	n	%	n	%	
Item 1	23	13.69	21	12.5	35	20.83	48	28.57	41	24.4	3.38 (1.34)
Item 2	2	1.19	1	0.6	12	7.14	111	66.07	42	25	4.13 (0.66)
Item 3	2	1.19	0	0	17	10.12	102	60.71	47	27.98	4.14 (0.69)
Item 4	2	1.19	0	0	15	8.93	83	49.4	68	40.48	4.28 (0.73)
Item 5	4	2.38	4	2.38	25	14.88	88	52.38	47	27.98	4.01 (0.86)
Item 6	2	1.19	4	2.38	8	4.76	53	31.55	101	60.12	4.47 (0.8)
Item 7	2	1.19	0	0	4	2.38	70	41.67	92	54.76	4.49 (0.67)
Item 8	1	0.6	0	0	2	1.19	58	34.52	107	63.69	4.61 (0.58)
Item 9	15	8.93	21	12.5	25	14.88	63	37.5	44	26.19	3.60 (1.25)
Item 10	0	0	1	0.6	11	6.55	58	34.52	98	58.33	4.51 (0.65)
Item 11	0	0	3	1.79	7	4.17	78	46.43	80	47.62	4.40 (0.66)
Item 12	1	0.6	1	0.6	11	6.55	74	44.05	81	48.21	4.39 (0.69)
Item 13	0	0	1	0.6	13	7.74	72	42.86	82	48.81	4.40 (0.66)
Item 14	0	0	5	2.98	29	17.26	90	53.57	44	26.19	4.03 (0.75)
Item 15	0	0	6	3.57	25	14.88	65	38.69	72	42.86	4.21 (0.83)
Item 16	0	0	0	0	3	1.79	27	16.07	138	82.14	4.80 (0.44)
Item 17	0	0	0	0	5	2.98	39	23.21	124	73.81	4.71 (0.52)
Item 18	0	0	1	0.6	4	2.38	53	31.55	110	65.48	4.62 (0.57)
Item 19	0	0	3	1.79	12	7.14	58	34.52	95	56.55	4.46 (0.71)
Item 20	0	0	0	0	6	3.57	69	41.07	93	55.36	4.52 (0.57)
Item 21	0	0	0	0	3	1.79	67	39.88	98	58.33	4.57 (0.53)
Item 22	0	0	0	0	0	0	53	31.55	115	68.45	4.68 (0.47)
Item 23	0	0	0	0	0	0	8	4.76	160	95.24	4.95 (0.21)
Item 24	0	0	0	0	1	0.6	38	22.62	129	76.79	4.76 (0.44)

With regard to the subscale Supporting students to learn, the mean total score was 63 (SD = 7.5), with a mean item score of 4.02 (SD = 0.88). Among the items in this dimension, Item 8, "I help students to learn the skills and develop the confidence required for midwifery practice," had the highest mean value (mean = 4.61; SD = 0.58). In contrast, Item 1, "I work collaboratively with university staff to achieve the best outcomes for students," had the lowest mean score (mean = 3.40), with a notable 20.83% of respondents indicating that they engaged in this behaviour only 'sometimes'.

For the Safety in learning subscale, which comprises nine items, the mean total score was 42.1 (SD = 2.7), and the corresponding item mean was 4.67 (SD = 0.53). The highest-rated statement was Item 23, "I intervene if a student's action, or inaction, is likely to compromise women's safety," with a mean score of 4.95. The majority of respondents (82.14%) selected 'always' for this item. The lowest mean within this dimension was reported for Item 19, "I consider the cultural values, beliefs, and practices of students when developing relationships with students", which had a mean score of 4.38 (Table 1).

Discussion

The present study provides the first Italian version of the MidPaACT tool, enabling the systematic exploration of midwife preceptors' perceptions of their educational role within clinical practice. The availability of a validated tool such as the I-MidPaACT enables the systematic evaluation of clinical teaching, which is essential for improving educational quality and accountability in midwifery education.

This study provides preliminary evidence supporting the structural validity and internal consistency of the Italian version of the instrument. Although the confirmatory factor analysis generally supported the original two-factor structure, the elevated SRMR suggests that model fit was not uniformly optimal and should therefore be interpreted with caution. Model fit indices should, however, be interpreted collectively rather than individually, as they reflect different aspects of model fit. In the present study, the excellent CFI and TLI values supported the overall adequacy of the hypothesised factorial structure, despite the higher SRMR value. Previous methodological literature suggests that the SRMR is particularly sensitive to local residual misspecification (Hu & Bentler, 1998). In this study, the elevated SRMR may partially reflect highly homogeneous response distributions and ceiling effects observed across several items, particularly in the Safety in learning domain.

Overall, midwives reported high self-perceived engagement in both supporting students' learning and ensuring safety in learning. These findings suggest that participants perceive themselves as actively involved in the educational aspects of clinical practice, consistent with the literature describing the preceptor as an important figure in shaping students' competence, confidence, and professional identity (Hughes & Fraser, 2011; Sheehan et al., 2022).

The high mean scores related to fostering skill development and intervening to protect women's safety suggest that Italian preceptors primarily perceive their role as safeguarding clinical standards while facilitating students' progressive autonomy. This dual focus is consistent with the broader professional expectations associated with midwifery practice, where responsibility toward attention to women and newborns coexists with responsibility for supporting the development of future professionals (International Confederation of Midwives, 2014; Kabirian et al., 2024).

These findings highlight the need for targeted faculty development initiatives to support preceptors in balancing clinical responsibilities with effective pedagogical practices. The high scores observed in the Safety in learning domain suggest that participants perceive patient safety as a central aspect of their preceptorship role. In particular, the very high ratings for items related to intervening when women's safety may be compromised indicate strong self-reported attention to clinical responsibilities. However, these findings should be interpreted with caution, as self-reported responses on safety-related items may also be influenced by social desirability bias. From an educational perspective, the prominence of safety-related perceptions highlights the importance of balancing patient safety with the creation of psychologically safe learning environments in which students feel supported to ask questions, reflect, and progressively assume responsibility (Neri et al., 2026; Sheehan et al., 2022).

Lower scores were observed in items related to

collaboration with university staff and attention to students' cultural values. The relatively low endorsement of collaboration with academic institutions may suggest opportunities to strengthen integration between university and clinical settings, a challenge widely discussed in health professions education in relation to the theory–practice gap (Griffiths et al., 2023).

Strong academic-clinical partnerships are recognised as essential for promoting coherent clinical education, aligning expectations, and supporting preceptors in their educational roles (International Confederation of Midwives, 2014; World Health Organization, 2021). Practical strategies may include structured communication channels, shared evaluation criteria, and joint faculty development initiatives.

The relatively lower score related to cultural responsiveness in mentoring relationships is noteworthy, especially in the context of increasingly diverse student populations. Considering that the supervisory relationship significantly influences students' emotional experience and professional growth (Neri et al., 2026), cultural sensitivity should be recognised as an integral component of effective mentorship rather than a secondary skill. Future educational initiatives for preceptors may benefit from incorporating reflective training on intercultural communication and inclusive supervision practices.

This finding is consistent with evidence suggesting that preceptors are often appointed primarily on the basis of clinical expertise rather than formal pedagogical preparation (Griffiths et al., 2021).

From a broader perspective, this study should be interpreted as part of a coherent trajectory in Italian midwifery educational research. Following the validation of the Italian version of the Midwifery Student Evaluation of Practice (MIDSTEP-IT) (Nespoli et al., 2024), which enabled the assessment of students' perceptions of clinical learning environments, the present validation of the I-MidPaACT enables the perspective of preceptors, complementing the student viewpoint. Together, these instruments provide a more holistic evaluation of clinical placement quality, moving beyond single-perspective assessment and supporting a systemic approach to educational quality improvement. This dual-perspective approach reflects a growing scholarly engagement among Italian midwives in enhancing educational standards through evidence-informed methodologies.

Strengths and limitations

A major strength of this study lies in providing a profession-specific, culturally adapted instrument for the Italian context, aligned with international validation standards. The inclusion of preceptors from multiple regions enhances the contextual relevance ecological relevance of the findings. Furthermore, confirmatory factor analysis using an estimator appropriate for ordinal data strengthens the methodological rigour of the validation process.

However, some limitations should be acknowledged. The sample was largely hospital-based and concentrated in three regions, which may limit the generalisability of the findings to community settings and other geographical contexts. Additionally, the cross-sectional design precluded the assessment of changes over time and potential associations between preceptors' perceptions and students' evaluations of the clinical learning environment. As the instrument relies on self-reported perceptions, responses may have been influenced by social desirability bias, particularly in relation to safety-related items. Moreover, although the present study provides preliminary evidence supporting structural validity and internal consistency, additional psychometric properties—including test–retest reliability, convergent validity, and responsiveness—were not assessed and should be explored in future studies.

Implications for practice and research

The availability of the I-MidPaACT offers Italian universities and clinical partners a structured means to monitor and reflect on the quality of mentorship within midwifery programmes. For example, the instrument could be integrated into routine programme evaluation processes, used to identify preceptors' educational support needs, and to inform targeted faculty development initiatives. At an organisational level, aggregated results could support academic–clinical quality improvement strategies and benchmarking across institutions.

Future studies could investigate how variables such as years of preceptorship experience, formal pedagogical training, or clinical setting influence

perceptions of the educational role. Longitudinal research could also clarify whether structured mentor training programmes lead to measurable improvements in both preceptor self-perception and student learning outcomes. Moreover, future research should examine the association between I-MidPaACT scores and MIDSTEP-IT results, thereby exploring concordance or discrepancies between student and mentor perspectives. Integrating both instruments into routine evaluation processes could support data-informed decision-making and contribute to the continuous quality improvement of clinical education in midwifery.

Conclusions

The Italian version of the MidPaACT demonstrates satisfactory preliminary psychometric properties for assessing midwife preceptors' perceptions of their clinical teaching role. Its availability fills a relevant gap in the Italian educational context by enabling the systematic inclusion of the preceptors' perspective in the evaluation of clinical placements.

The findings highlight a strong perceived commitment to supporting students' learning and ensuring safety in practice, while also identifying areas for further development, particularly in academic–clinical collaboration and culturally responsive supervision.

Used alongside the MIDSTEP-IT (Nespoli et al., 2024), the I-MidPaACT enables a dual-perspective assessment of clinical learning environments, supporting a more comprehensive and evidence-informed approach to strengthening midwifery education in Italy.

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Original Research

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Determinants of Career Advancement Among Medical Doctors in Italy: The Gender Gap

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Abstract

Introduction. Despite increasing numbers of women in medicine, they remain underrepresented in senior roles. Gender biases, lack of mentorship, work-family imbalance, and limited opportunities for advancement are among the factors that could hinder women's career progression in the field. The study aims to investigate factors associated with the gender gap in career advancement in the medical field in Italy. **Methods.** A cross-sectional study was conducted through a survey among the members of the Professional Order of the Physicians and Dental Surgeons of the Province of Rome from October 2023 to February 2024, focusing on career advancement, work-family balance, workload control, and harassment. Four different career paths were identified: Academic researchers and professors (ARP), Employees (EM), Self-employed medical doctors (SE), and Physicians practicing

in agreement with the NHS (PPAN). Descriptive analyses and multivariate logistic regression were run to assess factors influencing career progress and workplace experiences across various medical careers.

Results. A survey of 260 physicians found significant differences in career advancement: males, older physicians, and PPAN had higher odds of career advancement. Logistic regression showed that age, gender, and career type were associated with career advancement, with gender having a borderline significant interaction with having children. Work-family balance, exhaustion, and control over work had no significant impact on advancement. Harassment was reported more by women (36.4%) than men (17.2%), particularly in the EM subgroup, and greater control over work was significantly linked to lower harassment odds.

Discussion. A lower publishing rate among female academic hospital physicians and the impact of parenthood could be the reasons behind gender disparities in career progression between male and female medical doctors. Despite all other factors, being a woman is one of the most significant characteristics in shaping career progression.

Keywords: Gender Gap, Medical Doctors, Career Advancement, Inequalities, Barriers

Introduction

The issue of gender gap in our society and in the work environment is gaining space in academic and public debate.

In Europe and North America, the number of female physicians and women in medical research has increased considerably (Johannesen & Hagen, 2012; Buddeberg-Fischer et al., 2003), yet they are still underrepresented at senior levels, as well as in the editorial boards of major medical journals, and face barriers to academic career progression. (Fridner et al., 2015; Penny et al., 2014; Amrein et al., 2011).

In Italy, the percentage of women filling medical manager roles within the National Healthcare Service (NHS) went from 38.4% in 2010 to 48.1% in 2019, which rises to 64.0% considering personnel aged 35-44. However, both at the hospital and territorial level, 34.7% of women work in low-middle management and 17.2% are top managers (Ministero della Salute, 2021; OECD, 2020). Previous studies have confirmed the difficulty for women in Italy to reach leading positions in various medical fields, recognizing among the main determinant factors the presence of discriminatory practices, the lack of support and female networks, social expectations and gender roles hampering work-family balance (Larese Filon et al., 2019). The health academic field is no exception: women represent 32.7% of the academic staff, but the proportion of women is inversely proportional to the degree of career advancement (46.2% of researchers, 33.5% of associate professors and 19.1% of full professors are female) (MIUR; De Angelis & Grüning, 2020).

Previous studies have identified, among the possible reasons for the underrepresentation of women at senior levels in the medical field the clinical workload, the difficulty of having a mentor, a lower possibility of publishing their scientific works (House et al., 2021; Blood et al., 2012; Pololi et al., 2012) because of greater challenges in securing financial research support, and a lower representation of women in the editorial field and in scientific journals' boards (Lundine et al., 2018; Mayer et a., 2008; Valian, 1998). In the early defining stages of their careers, women are also less likely than men to hold full-time positions, possibly due to domestic tethers (Hitti et al., 2022), the presence of minor children at home and the feeling of

exhaustion due to the workload, factors that seem to penalize women more than men. (Fridner et al., 2015)

In the Italian context, the definition of career progression in the medical field is not homogeneous across different career paths, as it varies considerably between professional settings, depending on the characteristics of the organisation (i.e. Local Healthcare Units, Universities, Hospitals, ...) and the kind of employment contract. For career paths with hierarchical progression, such as academia and physicians practicing within the NHS, career advancement coincides with attaining the highest positions within the organization. In contrast, for career paths without upward mobility, the advancement may instead be measured by other factors, such as salary increases for General Practitioners or the number of working hours for Specialist Physicians.

Evidence on determinants of gender inequalities in career progression is essential to ensure adequate representation of women at the highest levels of the medical field. It is therefore necessary to broaden the investigation in different contexts to verify the presence of specific and contextual factors that influence women's career in the medical field. This study aims to investigate factors related to career advancement in the medical field in Italy with a focus on gender disparities.

Methods

Survey development and distribution

This cross-sectional study was carried out among medical doctor members of the Professional Order of the Physicians and Dental Surgeons of the Province of Rome (Ordine dei Medici Chirurghi e Odontoiatri di Roma OMCeO Roma), consisting of 41,553 people as of December 2024 (OMCeO Roma, 2024).

The survey was first published online on October 17, 2023 on the OMCeO-Roma website. Subsequently, the link to the anonymous questionnaire and a short introductory presentation of the study was sent via email as part of the weekly newsletter of the Order to all members. Two reminders were sent and the questionnaire remained available until February 29, 2024. Due to the low response rate, further ad hoc reminders were sent to increase participation throughout March 2024. Given the survey dissemination procedure, the study relies on a non-probabilistic self-selected sample.

The questionnaire was developed based on the one from Fridner et al., 2015, translated into Italian, and adjusted for the different target populations. The translated questionnaire had previously been used by a research group at the University of Padua, originally involved in the HOUPE study, a longitudinal research program on work-related health, organizational culture, career paths, and working conditions in university hospitals in Sweden, Norway, Iceland, and Italy. It was structured into two main sections: the first section investigated sociodemographic characteristics such as marital status, number of children, and basic information about the type of medical career, and was the same for all participants; the second section was articulated in four different branches, reflecting the different medical careers, and investigated specific characteristics of each job, working position, workload and control over work, work-family balance, work environment and harassment, and physical and mental health and wellbeing.

The different medical careers were labeled as Academic researchers and professors (ARP), Employees (EM), Self-employed medical doctors (SEMD), and Physicians practicing in agreement with the NHS (PPAN), this last category including General Practitioners (GP), General Paediatrician, and Specialist Physicians.

The working position for ARP was identified either as full or assistant professor, whereas for EM it was classified as head physician, permanent medical officer or fixed-term medical officer. SEMD and PPAN are characterized by no differentiation in working position, and therefore, no information related to working position was retrieved.

Control over work and exhaustion were assessed through the items considered by Fridner et al., 2015 of the "Nordic Questionnaire for Psychological and Social Factors at Work" (QPS Nordic) and "Mini Oldenburg Burnout Inventory" (MOLBI), respectively. Each item was obtained on a Likert scale and a summary measure was calculated as the mean response score per person.

The work-family balance score was dichotomised as "Poor" or "Good" according to

the Likert scale score to the question "My work prevents me from taking care of my family activities as much as I would like". Answers "partially agree" and "completely agree" were categorised as "Poor", whereas "partially disagree" and "completely disagree" were categorised as "Good".

ARP and EM were also asked about control over workload and work management within their organisations.

Variables

The main outcome was "career advancement", a dichotomous variable which was identified differently for each professional category. For the ARP, positive career advancement was identified as being a professor, for EM as being the head of a department of the local healthcare unit, for SEMD as earning more than 5000€ per month, whereas for PPAN the cut-off for the definition of career advancement was considered to have at least 1500 patients, which is the maximum allowed number of patients for a single GP or General Paediatrician, or having a 38 hours per week work shift for Specialist Physicians, which is the maximum amount of working hours set by law for this kind of contracts, meaning that they reached the peak of their activity.

A secondary outcome was having experienced harassment on the job in the last six months. The definition of harassment was an offensive behavior that "[...] has to occur repeatedly over a period of time, and the person confronted has to experience difficulties defending himself/herself".

The qualitative variables, such as sex, marital and parental status, and career advancement were dichotomized, whereas age, control over work and exhaustion were analyzed as continuous variables.

Statistical Analyses

A descriptive analysis was conducted to identify the sociodemographic characteristics of the sample, as well as work-family balance, control at work, and exhaustion. Percentages were estimated for categorical variables, whereas mean and standard deviation or median and interquartile ranges were calculated for continuous variables. Univariate analysis between dependent and independent variables was run through $\chi 2$ or Fisher's exact test. Two multivariate logistic regression models were built including all the variables with a statistically significant association with p-value <0.25 and those of epidemiological interest. The first multivariable logistic regression model was conducted to understand the influence of the independent variables of age, gender, marital status, presence of children, type of medical career and work-family balance on the primary outcome, i.e. career advancement. The interaction between sex and having children was also added to the model.

The second multivariable logistic regression model focused on the influence of the independent variables of working position, age, sex, level of exhaustion, and control over work on the secondary outcome, which was experiencing episodes of harassment at the workplace.

A p-value <0.05 was considered significant for all analyses. The odds ratio (OR) and 95% confidence interval (95% CI) were calculated for each independent variable. The statistical analyses were done through STATA 18 (Stata Corporation, College Station, TX, USA).

Ethical approval

Ethical approval for this study was obtained from the Ethics Committee for Transdisciplinary Research of Sapienza University of Rome (determination 49/2023) on 17/03/2023.

Results

A total of 260 physicians responded to the survey. The majority of them (41%) were EM, followed by ARP (24%), PPAN (18%) and SEMD (13%) The characteristics of the respondents are reported in Table 1.

In the univariate analysis (Table 2), statistically significant differences in career advancement were observed according to gender, age, and type of medical career (for the definition of career advancement for different medical careers, see the Methods section). Male doctors reported career advancements significantly more frequently than females (33.3% vs. 15.9%, p=0.002). Likewise, older physicians were more

Table 1. Characteristics of the sample.

Characteristics		Total, n (%)	ARP, n (%)	EM, n (%)	PPAN, n (%)	SEMD, n (%)	Other, n (%)
Number of respondents		260	63 (24.2)	106 (40.8)	47 (18.1)	34 (13.1)	10 (3.9)
Sex	Female	182 (70.0)	34 (54.0)	83 (78.3)	34 (72.3)	24 (70.6)	7 (70.0)
	Male	78 (30.0)	29 (46.0)	23 (21.7)	13 (27.7)	10 (29.4)	3 (30.0)
Age group	Median (Q1-Q3)	49 (39.5-62)	53 (30-77)	44.5 (26-71)	60 (25-71)	54 (30-75)	42 (27-71)
Civil status	In a relationship	215 (82.7)	55 (87.3)	85 (80.2)	41 (87.2)	26 (76.5)	8 (80.0)
	Not in a relationship	45 (17.3)	8 (12.7)	21 (19.8)	6 (12.8)	8 (23.5)	2 (20.0)
Children	Yes	165 (63.5)	46 (73.0)	59 (55.7)	36 (76.6)	19 (55.9)	5 (50.0)
	No	95 (36.5)	17 (27.0)	47 (44.3)	11 (23.4)	15 (44.1)	5 (50.0)
Career advancement	Yes	55 (21.1)	10 (15.9)	14 (13.2)	22 (46.8)	9 (26.5)	0 (0.0)
	No	205 (78.9)	53 (84.1)	92 (86.8)	25 (53.2)	25 (73.5)	10 (100.0)
Work-family balance	Poor	45 (17.3)	11 (17.5)	14 (13.2)	8 (17.0)	10 (29.4)	2 (20.0)
	Good	215 (83.0)	52 (82.5)	92 (86.8)	39 (83.0)	24 (70.6)	8 (80.0)
Control at work	Median (Q1-Q3)	2.67 (2-3.3)	3 (2.2-3.5)	2.5 (1.7-3.2)	NA*	NA*	2.67(2.3-3.2)
Exhaustion	Mean (SD)	2.79 (0.32)	2.73 (0.38)	2.80 (0.31)	2.83 (0.30)	2.81 (0.27)	2.74 (0.28)

Legend. NA: not attributable. ARP: Academic researchers and professors; EM: Employees; PPAN: Physicians practicing in agreement with the National Healthcare Service; SEMD: Self-employed medical doctors.

likely at a higher career level, with a median age of 62 years old (Q1-Q3=53-68) among those reporting career advancement vs. 46 years old (Q1-Q3=38-59) of those who did not (p<0.001). PPAN were significantly more represented among the career advancement group (46.8%) compared to all other categories of medical career (SEMD 26.5%, ARPs 15.9 %, EM 13.2 %, p<0.001). Differences in work-family balance, control over work and exhaustion were not statistically significant among the two groups.

The logistic regression model, which included age, gender, marital status, children, type of medical career and work family balance, showed that older age, being male, and being employed as PPAN were associated with career advancement (Table 3). When considering the possible interaction between gender and having children, though gender was not a statistically significant predictor, the interaction term was borderline significant (Table 4).

When adding control over work to the model (which restricted the sample only to ARP and EM), the interaction term remained a statistically significant predictor of career advancement (OR 0.05, p=0.048) (Table 5).

We analyzed the association of experiencing harassment in the workplace with gender. The association was statistically significant with 36.42% of women reporting harassment in the workplace compared to 17.24% of men (p=0.001). This relationship was observed also in the EM subgroup (48.19% of women and 17.39% of males reported being harassed, p=0.008), where we investigated the role of potential predictors of harassment as well, such as working position,

Table 2. Results from the univariate analysis.

		Career advancement		
Characteristics		No (%) n=205	Yes (%) n=55	p-value
Sex	Female	153 (84.1)	29 (15.9)	0.002
	Male	52 (66.7)	26 (33.3)	
Age group	Median (Q1-Q3)	46 (38-59)	62 (53-68)	0.000
Civil status	In a relationship	169 (78.6)	46 (21.4)	0.835
	Not in a relationship	36 (80.0)	9 (20.0)	
Children	Yes	127 (77.0)	38(23.0)	0.272
	No	78 (82.1)	17 (17.9)	
Type of medical career	ARP	53 (84.1)	10 (15.9)	0.000
	EM	92 (86.8)	14 (13.2)	
	PPAN	25 (53.2)	22(46.8)	
	SEMD	25 (73.5)	9 (26.5)	
	Other	10 (100.0)	0 (0.0)	
Work-family balance	Poor	32 (71.1)	13 (28.9)	0.162
	Good	173 (80.5)	42 (19.5)	
Control at work	Median (Q1-Q3)	2.67 (1.83-3.33)	3 (2.33-3.58)	0.090
Exhaustion	Mean (SD)	2.79 (0.32)	2.78 (0.29)	0.848

Legend. ARP: Academic researchers and professors; EM: Employees; PPAN: Physicians practicing in agreement with the National Healthcare Service; SEMD: Self-employed medical doctors.

Table 3. Result from the multiple logistic regression analysis (without interaction term).

	Odds ratio	SE	95% CI	p-value
Age	1.08	0.02	1.05-1.12	<0.001
Gender (ref. Male)	0.36	0.14	0.17-0.76	0.007
Marital status (ref. not married)	1.30	0.61	0.51-3.28	0.584
Children (ref. no children)	0.51	0.22	0.23-1.17	0.113
Type of medical career (ref. ARP)				
SEMD	1.82	1.11	0.56-5.99	0.322
PPAN	6.44	3.29	2.37-17.52	<0.001
EM	1.51	0.75	0.57-4.02	0.411
Work-family balance (ref. low)	1.03	0.47	0.42-2.50	0.947

Legend. ARP: Academic researchers and professors; EM: Employees; PPAN: Physicians practicing in agreement with the National Healthcare Service; SEMD: Self-employed medical doctors.

Table 4. Results from the multiple logistic regression analysis for career advancement.

	Odds ratio	SE	95% CI	p-value
Age	1.08	0.02	1.05-1.12	<0.001
Gender (ref. Male)	1.13	0.81	0.27-4.68	0.871
Marital status (ref. not married)	1.31	0.63	0.51-3.37	0.566
Children (ref. no children)	1.63	1.21	0.38-6.96	0.508
Interaction term Children-gender	0.18	0.16	0.03-1.00	0.050
Type of medical career (ref. ARP)				
SEMD	1.88	1.16	0.56-6.28	0.307
PPAN	7.27	3.84	2.57-20.47	<0.001
EM	1.63	0.84	0.59-4.48	0.342
Work-family balance (ref. low)	1.03	0.47	0.42-2.54	0.936

Legend. ARP: Academic researchers and professors; EM: Employees; PPAN: Physicians practicing in agreement with the National Healthcare Service; SEMD: Self-employed medical doctors.

control over work and exhaustion, using a multiple logistic regression model (Table 6). The analysis showed that the only statistically significant predictor of experiencing harassment at the workplace was control over work, with higher levels of control associated with lower odds of experiencing harassment.

Table 5. Result from the multiple logistic regression analysis with interaction term and control over work (restricted to ARP and EM).

	Odds ratio	SE	95% CI	p-value
Age	1.18	0.04	1.10-1.27	<0.001
Gender (ref. Male)	2.19	2.77	0.18-26.28	0.538
Marital status (ref. not married)	0.98	0.65	0.27-3.61	0.977
Children (ref. no children)	5.61	7.43	0.42-75.23	0.193
Interaction term Children-gender	0.05	0.07	0.00-0.97	0.048
Type of medical career (ref. ARP)				
EM	3.89	2.72	0.98-15.34	0.053
Work-family balance (ref. low)	1.13	0.81	0.28-4.57	0.864
Control over work	1.45	0.52	0.72-2.95	0.299

Legend. ARP: Academic researchers and professors; EM: Employees.

Table 6. Result from the multiple logistic regression analysis for harassment in the workplace.

	Odds ratio	SE	95% CI	p-value
Gender (ref. Male)	3.27	2.20	0.88-12.21	0.078
Age	1.02	0.02	0.98-1.07	0.322
Working position (ref. Head physician)				
Permanent Medical Officer	1.07	0.77	0.27-4.35	0.920
Fixed-term Medical Officer	2.41	2.24	0.39-14.92	0.346
Control over work	0.42	0.12	0.24-0.74	0.002
Exhaustion	0.98	0.74	0.22-4.37	0.987

Discussion and conclusions

This research attempts to depict the characteristics of career advancement in a sample of medical doctors in four different career paths in Italy. Our findings suggest that, being older, being male and working as a PPAN is associated with higher odds of career advancement. Academic work appears to be associated with lower career advancement odds than all other career paths. Having children appeared to have a differential impact on male and female physicians, while work-family balance did not seem to be significantly associated with career advancement when adjusting by the other factors.

In our sample, being a male was significantly associated with higher odds of career advancement, which aligns with the literature on the subject. Although there is evidence that gender disparities also exist in non-academic medical career paths (Weil et al., 1996; De Rosa et al., 2024; Bosco et al., 2020), the majority of the literature on the subject has focused on academic career opportunities for medical doctors (Bennett et al., 2019; Collazo et al., 2024; Lee et al., 2023; Hunter et al., 2021; Sharma et al., 2025; Khatib et al., 2024; De Paola, 2024). Publishing rate is an essential element that can generate disparities between the genders (Kaufman & Chevan, 2011) among academic hospital physicians (Løvseth et al., 2014). According to a global analysis, women contribute to approximately 30% of scientific publications. (Larivière et al., 2013) Even in Italy, the scientific production of women is lower than that of their male colleagues. A similar gender publication gap is evident when considering publications with a woman as the first author (Abramo et al., 2009; Jagsi et al., 2006). A multicenter study compared the volume of publications of male and female medical personnel in Norway, Sweden, and Italy. In all three samples, men published more than women. This phenomenon was more emphasized when considering publications as first or last authors. (Løvseth et al., 2014) Similarly, an analysis of the Italian scientific production regarding COVID-19 throughout the first months of the health emergency revealed a low prevalence of studies with a female first or last author (Mazzalai et al., 2022). Possible reasons for this include gender-based discrimination and structural barriers such as limited access to established networks, lower access to quality mentorship and difficulty in gaining funds for research. Moreover, studies suggest balancing work and family responsibilities could play a role in this pattern

(Larese Filon et al., 2019; House et al., 2021; Hitti et al., 2022; Rosa et al., 2024; Bosco et al., 2020).

In fact, having children or being married did not seem to influence career advancement in our multiple regression analyses, although the interaction between gender and having children turned out to be statistically significant. This seems to point to the differential impact that being a parent has on male and female physicians. This is well acknowledged, and the literature showed how parenthood impacts more heavily on women's rather than men's career, widening the pay gap between sexes, and its substantial persistence over the lifecycle (Angelov et al., 2016; Goldin et al., 2024).

Working in the academic field was independently associated with lower odds of career advancement in the multiple regression models compared to other career paths, although these differences were not always statistically significant. In particular, being PPAN was associated with higher odds of career advancement. This could be partly attributed to the way in which career advancement was measured for PPAN, with a high proportion of medical doctors in this field having reached the maximum number of patients or hours of contract. Indeed, in Italy the average number of GPs per 1000 inhabitants is 0.69, meaning that each doctor has on average more than 1449 patients. In the Lazio Region, where the analysis was conducted, the rate is slightly higher (0.71 GP/1000 inhabitants), but still the share of patients is very close to the maximum number allowed. The situation is similar for General Pediatricians (ISTAT, 2025).

When excluding the influence of gender, work-family balance did not appear to have a significant impact. Even though evidence on the topic is scarce and often unclear, these results do not seem to align with recent evidence highlighting how a better work-life balance and job satisfaction positively influence career advancement, at least for managers (Lyness & Judiesch, 2008). Another study showed how work-life balance was positively associated with career opportunities, even though women reported lower scores for both work-life balance and career opportunities (Pace & Sciotto, 2022). However, based on our results, the disadvantage that women experience is not only related to a heavier burden of domestic duties and difficulties in balancing work with family life, but rather to other factors that would deserve further investigation.

Control over work did not seem to play a significant role in career advancement either, nor did it play a significant role in the univariate analyses in the whole sample or in the multiple logistic regression for ARP and EM. By contrast, the study by Fridner et al., 2015 showed that control over work was an important predictor of publishing rate (in turn associated with career advancement) in medical doctors with a PhD and that men experienced higher control than women.

Our analyses suggest that experiencing harassment in the workplace could be associated with gender, with women experiencing harassment more frequently than their male colleagues. When analyzing a wider range of possible determinants in the employed subgroup, control over work seemed to be the only significant predictor of experiencing harassment. This seems to point to the fact that physicians experiencing lower levels of control over their work are more subject to harassment. In this subsample, the relationship between control over work and working position is u-shaped, with lower mean levels of control being reported in the permanent medical officers. The small sample size could partly explain the lack of statistical significance of gender in the multiple regression analysis.

The study has some limitations which should be acknowledged. The response rate from the study sample was low, around 0.63%, and the sample size small. Therefore, the effect of certain factors could not be estimated precisely. Moreover, the sample size has limited the possibility to analyze in further detail the determinants of career advancement for each career path, such as, for example, specific working positions or medical fields (surgical, diagnostic, etc.). The sampling strategy may have been affected by selection bias, as participation was self-selected due to the survey dissemination methods. Consequently, individuals with a stronger interest in the topic, and potentially those more affected by gender disparities, may have been more likely to take part in the survey.

Finally, career advancement was dichotomized for all career paths, according to the progression in job roles for ARP and EM, reaching the maximum number of patients or hours for PPAN, and reaching a salary threshold for SEMD. This allowed us to compare different career paths,

although inevitably overlooking peculiarities in each path.

To our knowledge, this is the first study analyzing the factors influencing career advancement in medical doctors in the Italian context with a gender perspective. It provides an overview of the current situation for different career paths in the medical field and identifies critical areas for improving current working conditions in the medical field. Even though the access of women to the medical field has increased and reached that of men, inequalities persist when looking at senior positions. Moreover, women are more likely to experience harassment in the workplace. Even though the understanding of the underlying factors remains limited, gender appears to be the strongest determinant of power imbalance.

This research could serve as a starting point for further investigations in this area. Further studies are needed to provide evidence on the reasons behind the role of gender in hampering the career progression of women. Future research should include a focus on career-specific analyses to better understand each work environment's specific characteristics.

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Emergency Department Nurses' Experiences with the Early Care Pathway (ECP) Model: An Interpretative Phenomenological Study

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Abstract

Introduction. The Early Care Pathway (ECP) model was recently introduced in some emergency departments (EDs) in Northern Italy to enhance patient care through earlier nursing intervention. Although its benefits are recognized, little is known about how nurses experience and adapt to this organizational innovation. This study explores emergency nurses' lived experiences with the ECP model, focusing on its impact on practice, professional identity, and interprofessional collaboration.

Methods. A qualitative study was conducted using Interpretative Phenomenological Analysis (IPA). Seventeen nurses (12 females, 5 males; age range 24–55) with direct experience of the ECP model participated in semi-structured interviews between July and August 2024. Participants were purposively

selected based on criteria including ECP training and at least three months of experience using the model. Interviews were audio-recorded, transcribed verbatim, translated into English, and analyzed following the IPA framework. Rigor was ensured through bracketing, audit trails, member checking, and triangulation.

Results. Five interrelated themes emerged: (1) Deepening the nurse-patient connection – The ECP model enhanced the quality of interaction, promoting empathy, trust, and patient satisfaction through focused, uninterrupted time; (2) Empowerment and professional identity growth – Nurses reported increased autonomy, recognition, and decision-making capacity. The model reinforced their clinical judgement and enabled a more meaningful expression of their role; (3) Streamlining care through organizational innovation – ECP improved care efficiency by transforming waiting time into active care, promoting faster interventions and optimized workflows; (4) Fostering communication and team synergy – The model enhanced interdisciplinary collaboration and improved nurse-doctor dialogue. Nurses experienced more fluid team communication and greater involvement in early care decisions; (5) Navigating challenges and overcoming barriers – Implementation obstacles included resistance from physicians, ambiguity in role delineation, and workload concerns. However, most nurses expressed that these challenges were outweighed by the model's benefits.

Conclusion. The ECP model has a transformative impact on emergency nursing, fostering deeper patient relationships, enhancing professional identity, streamlining care, and strengthening teamwork. While implementation challenges exist, nurses overwhelmingly view the model as a valuable innovation that enriches both patient care and their professional experience. Understanding these lived experiences is essential for guiding future implementations and addressing contextual barriers.

Keywords: Emergency Service, Hospital, Nursing, Qualitative Research, Professional Role, Interprofessional Relations, Patient-Centered Care

Introduction

Emergency Departments (EDs) serve as pivotal entry points in the healthcare system, managing a broad spectrum of clinical conditions and providing timely diagnostic, therapeutic, and stabilization services. In Italy, the ED is mandated to perform not only urgent diagnostic and therapeutic interventions but also the initial clinical, instrumental, and laboratory assessments, stabilization of the patient, and the protected transport (Presidenza della Repubblica Italiana, 1992). EDs represent a crucial component of the Italian National Health Service, ensuring immediate access to acute care. However, in recent years, EDs have faced growing pressure due to a substantial increase in patient visits, many of which are classified as non-urgent. In 2023, Italian EDs managed approximately 18.27 million visits, 68% of which were classified as white or green codes, indicating non-urgent or low-acuity conditions (AGENAS, 2022). This

high volume of predominantly low-acuity presentations contributes to overcrowding, with potential consequences including prolonged waiting times, increased clinical risk, and elevated stress among healthcare professionals.

The inappropriate use of EDs is a globally recognized challenge (Kim et al., 2024), prompting national and regional authorities to seek organizational innovations to streamline patient flow and safeguard quality of care. Several studies have highlighted the effectiveness of nurse-led interventions and early care pathways in improving patient flow, reducing waiting times, and enhancing clinical outcomes (Burgess et al., 2021; Considine et al., 2019; Varndell et al., 2018). In response, models such as the Fast Track pathway have been developed, targeting patients with low clinical complexity to reduce unnecessary delays (AGENAS, 2022).

Within this evolving landscape, the Early Care Pathway (ECP) model has emerged as a promising solution. Unlike traditional workflows, the ECP enables selected patients, following triage, to begin clinical-care protocols initiated by triage nurses or specially trained personnel, without waiting for a physician's assessment (Douma et al., 2016). These nurse-led protocols typically include early diagnostic testing and analgesic administration, particularly in cases involving trauma or acute pain (Burgess et al., 2021; Considine et al., 2019; Varndell et al., 2018). When implemented effectively, ECPs can mitigate the consequences of ED overcrowding by accelerating the care process and enhancing patient safety (Borghetti et al., 2021). Empirical evidence underscores the clinical benefits of ECP protocols. For instance, Douma et al. (2016) found that nurse-initiated pathways reduced the time to analgesic administration by 186 minutes, the time to diagnostic testing for chest pain by 79 minutes, and the length of stay for hip fractures by 224 minutes (Douma et al., 2016). These data support the efficiency and safety of early nursing interventions within emergency workflows.

Beyond organizational aspects, the implementation of the ECP model can also be interpreted through theoretical perspectives related to nursing professional identity, autonomy, and relational care. Professional identity in nursing is considered a dynamic construct shaped by clinical practice, responsibility, and interprofessional interactions (Chenou et al., 2025; Gawthorne et al., 2025). Models that expand nurses' decision-making capacity, such as the ECP, may contribute to strengthening this identity. In addition, nursing autonomy is closely linked to the ability to exercise clinical judgment and act independently within defined protocols (Gawthorne et al., 2025). The introduction of nurse-led pathways challenges traditional hierarchical models and supports more collaborative approaches to care. Finally, relational care frameworks emphasize the importance of communication, empathy, and the nurse–patient relationship (Santana et al., 2018; Walsh et al., 2022). In emergency settings, these dimensions are often constrained by time pressures, and the ECP model may reshape how relational care is delivered.

In Italy, these models are increasingly supported by national and regional regulations aimed at strengthening organizational pathways and expanding nursing competencies in emergency care. These reforms reflect a broader effort to enhance the role of nurses in acute care delivery and improve the efficiency of EDs. Several EDs in Lombardy have drawn inspiration from the Triage Nurse Ordering model, leveraging nurse-led ECPs to transform passive waiting into active clinical intervention (Rowe et al., 2011). This approach not only optimizes patient flow but also improves satisfaction and clinical outcomes.

Despite the promising outcomes reported in quantitative research, little is known about how nurses subjectively experience and make sense of implementing ECP protocols in everyday emergency care. Understanding these experiences is important for the sustainable adoption of nurse-led pathways, particularly because ECP implementation may reshape professional identity, relational care, clinical autonomy, and interprofessional dynamics. Therefore, this study adopted an interpretative phenomenological approach to explore how ED nurses in Northern Italy make sense of their lived experiences with the ECP model, with particular attention to meaning-making processes related to professional identity, relational care, and organizational change.

Methods

Study design

This study was conducted and reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ)

guidelines (Tong et al., 2007), which is provided in supplementary material.

This study utilized a qualitative design based on Interpretative Phenomenological Analysis (IPA), a method well-suited for capturing rich, in-depth perspectives and the meanings participants attach to their experiences (Smith & Fieldsend, 2021). IPA enables researchers to explore the subjective world of participants, focusing on how they make sense of their experiences (Smith & Fieldsend, 2021). This approach aligns closely with the study's aim of providing a nuanced understanding of how ED nurses adapt to the innovative ECP model (Smith, 2011). IPA's dynamic and interactive nature allows consideration of both participants' viewpoints and researchers' interpretative analyses, capturing the complex interplay between experience and meaning (Smith et al., 2021; Smith & Fieldsend, 2021). This approach guided both data collection and analysis, with a focus on understanding participants' subjective meaning-making and the interpretative role of the researchers.

Setting and participants

The study was conducted in a high-volume Emergency Department located in Milan, Northern Italy, where the ECP model had been recently implemented. The department manages approximately 60,000 patient admissions per year and represents a key access point for acute care within the regional healthcare system. Participants were recruited using a combination of purposive and convenience sampling. Purposive sampling was employed to identify nurses with direct experience of the ECP model, in line with the study aim. Convenience sampling was used to facilitate recruitment within the clinical setting, allowing access to participants available during the data collection period. This combined approach ensured both the relevance of participants' experiences and the feasibility of recruitment (Sasso et al., 2025). Participants were approached face-to-face within the clinical setting and provided with information about the study before consenting to participate. No participants refused to participate or withdrew from the study.

The sample size was not defined a priori but was guided by the concept of information power, consistent with the focused and idiographic orientation of the study. Given the specificity of the sample, the narrow study aim, participants' direct experience of the ECP model, and the richness of the interview accounts, recruitment continued until the dataset provided sufficient depth and experiential variation to support a nuanced exploration of the phenomenon. Inclusion criteria were: a) registered nurses with current licensure in Italy; b) at least three months of experience working in an ED with the ECP model; c) formal training in triage and ECP protocols; d) willingness to participate and provide informed consent. Exclusion criteria were: a) nurses without formal triage training; b) nurses lacking direct experience with the ECP model; c) nurses with less than three months of ED experience; d) nurses who declined to provide informed consent. A total of 17 nurses participated in the study.

Data collection

Data were collected between July and August 2024 through in-depth, semi-structured interviews (Sasso et al., 2025), selected for their capacity to elicit rich and nuanced accounts of how participants experienced and interpreted the ECP model. No repeat interviews were conducted. Field notes were recorded during and immediately after each interview to capture contextual observations and support interpretation of participants' accounts. Interviews were conducted in private, quiet locations within the hospital to ensure confidentiality and participant comfort. Each interview lasted between 20 and 40 minutes and concluded when participants felt they had fully expressed their thoughts. All participants provided written informed consent prior to the interviews, which were audio-recorded and transcribed verbatim to guarantee accuracy. To deepen the exploration, follow-up prompts encouraged participants to elaborate on their responses. The interview guide, presented in Table 1, consisted of open-ended questions designed to investigate nurses' perceptions, challenges, and perceived benefits of the ECP model.

Table 1. Interview Guide.

Section 1: Introduction
"Thank you for agreeing to participate in this interview. The aim of this conversation is to explore your experiences and perspectives related to the implementation of the Emergency Care Practitioner (ECP) model in your department. There are no right or wrong answers. Please feel free to share your thoughts openly. Everything you say will be kept confidential and used only for research purposes."
Section 2: Opening Questions
1. ***Can you briefly describe your professional background and current role in the emergency department?***
2. ***When and how did you first become involved with the ECP model?***
Section 3: Core Questions
3. ***Can you describe your professional experience with the introduction of the ECP model?*** *Follow-up: What were your initial expectations or concerns?*
4. ***Have you observed any emotional or psychological impact on your professional practice following the implementation of the ECP model?*** *Follow-up: How did it affect your motivation, stress levels, or job satisfaction?*
5. ***In your opinion, how has the ECP model influenced the quality of care provided to patients in the emergency department?*** *Follow-up: Could you provide any specific examples?*
6. ***How do you believe the ECP model has affected relationships and collaboration between you and other members of the emergency team?*** *Follow-up: Have there been changes in communication, decision-making, or team dynamics?*
7. ***What were the main obstacles or challenges you encountered during the implementation of the ECP model?*** *Follow-up: How were these challenges addressed, if at all?*
8. ***From your perspective, what benefits or advantages have you observed since the introduction of the ECP model?*** *Follow-up: Were any of these unexpected?*
9. ***Which improvements or modifications would you suggest for the future implementation and refinement of the ECP model?*** *Follow-up: What advice would you give to another department planning to adopt it?*
Section 4: Closing Questions
10. ***Is there anything else you would like to add or think is important for us to understand about your experience with the ECP model?***
11. ***Would you be open to a follow-up conversation if further clarification is needed?***

Data Analysis

All audio recordings were meticulously transcribed verbatim by one author (SH). The translation process from Italian to English was carefully conducted to preserve the original meaning and interpretative depth of participants' narratives. The initial translation was performed by one researcher (SH) and subsequently independently reviewed by a second researcher (LG) to ensure semantic accuracy and consistency. This process involved researcher triangulation, whereby both researchers compared the translated texts with the original transcripts to verify fidelity to participants' meanings. Any discrepancies or ambiguities were discussed and resolved collaboratively, ensuring that the final version accurately reflected the nuances of the original data while maintaining interpretative coherence.

Data analysis was conducted by two researchers (SH and LG), who independently engaged with the transcripts and subsequently discussed emerging interpretations to reach a shared understanding. Themes were inductively derived from the data. No qualitative data analysis software was used. Data were analyzed following the principles of IPA as outlined by Smith et al. (2021) (Smith et al., 2021). The analytic process was iterative, inductive, and idiographic, with a focus on understanding how individual participants made sense of their lived experiences with the ECP model. Each transcript was first analyzed independently to preserve the idiographic commitment of IPA. This involved repeated close reading and detailed exploratory commenting, including descriptive, linguistic, and conceptual notes. Particular attention was paid to the meanings participants attributed to their experiences, as well as to the emotional and relational dimensions embedded in their narratives. Emergent themes were then developed for each individual case, capturing both explicit statements and underlying meanings. This phase involved a double hermeneutic process, whereby the researchers engaged in interpreting how participants themselves interpreted their experiences.

Subsequently, patterns across cases were

examined, identifying convergences and divergences while maintaining sensitivity to individual nuances. Themes were organized into superordinate themes and related sub-themes, reflecting both shared experiential structures and individual meaning-making processes.

Throughout the analysis, discussions among the research team supported the interpretative process, ensuring that findings remained grounded in the data while acknowledging the researchers' active role in meaning construction.

Rigour and reflexivity

To strengthen the rigor and trustworthiness of the analysis, multiple strategies were implemented. Bracketing was employed to consciously acknowledge and set aside researchers' preconceptions, ensuring interpretations remained grounded in participants' lived experiences. Audit trails were meticulously maintained to transparently document every phase of the analytic process, enhancing reproducibility and clarity. Additionally, thick descriptions were provided, offering rich, contextually detailed accounts that deepen the understanding and transferability of the findings within the participants' environment. The researchers' backgrounds and positioning were considered throughout the study in line with IPA principles. The research team consisted of nurse researchers with experience in emergency care and qualitative research. This professional background facilitated access to the field and a deep understanding of the clinical context, while also requiring careful reflexive awareness. To address this, reflexivity was actively practiced throughout the research process. Researchers engaged in bracketing to critically reflect on their assumptions, and regular team discussions were conducted to examine alternative interpretations and ensure that findings remained grounded in participants' accounts.

In addition, this study adhered to Lincoln and Guba's (1988) established criteria for qualitative rigor: credibility, transferability, dependability, and confirmability (12). Credibility was ensured through prolonged engagement with the data, allowing a comprehensive understanding of participants' perspectives, member checking, and methodological triangulation. Member checking was conducted after the preliminary analysis phase by sharing initial interpretations and emerging themes with a subset of participants. Participants were asked to review whether the interpretations accurately reflected their experiences and meanings. Feedback received was used to refine and confirm the analysis, ensuring that the findings remained grounded in participants' perspectives. Triangulation was achieved by cross-referencing diverse data sources, such as interview transcripts and field notes, to strengthen the robustness and accuracy of the analysis. Feedback received was incorporated into the final analysis. Triangulation was achieved by cross-referencing diverse data sources, such as interview transcripts and field notes, to strengthen the robustness and accuracy of the analysis. Transferability was addressed by offering detailed contextual descriptions of the study setting, participant profiles, and key results, enabling readers to evaluate the applicability of findings to other contexts. Dependability was supported through thorough audit trails that recorded every step of data collection, analysis, and interpretation, guaranteeing transparency and methodological consistency. Confirmability was enhanced through ongoing reflexivity and the use of bracketing, whereby researchers actively minimized personal biases, thereby preserving the objectivity of the study and ensuring that the results accurately reflect the participants' narratives.

Ethical considerations

The study complied with the Declaration of Helsinki (2013), including Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR) and the Italian Privacy Code (Legislative Decree No. 196/2003, amended by Law No. 56/2024). Participants were fully informed about the study's aims, procedures, possible risks, and their right to withdraw at any time without penalty. All data were anonymized, and confidentiality was rigorously maintained throughout. Ethical approval was obtained from the appropriate institutional review board.

Results

The sample included 17 nurses (12 females, 5 males) aged 24 to 55 years (mean 46), with diverse professional backgrounds ranging from recent graduates to veterans with over 30 years of experience. Educational levels varied from

diploma holders to nurses with bachelor's degrees and postgraduate qualifications, including master's degrees (see Table 2 for details).

Table 2. Population description.

Nurses	Age, Sex	Work	Educational Qualification
1	55 years, female	27 years	Diploma, Master's degree
2	53 years, female	33 years	Diploma
3	50 years, female	27 years	Diploma
4	53 years, female	27 years	Diploma
5	29 years, female	5 years	Bachelor's degree
6	29 years, female	4 years	Bachelor's degree
7	30 years, female	5 years	Bachelor's degree, Master's degree
8	24 years, female	2 years	Bachelor's degree
9	27 years, female	4 years	Bachelor's degree
10	27 years, female	4 years	Bachelor's degree
11	30 years, female	5 years	Bachelor's degree
12	33 years, male	8 years	Bachelor's degree
13	28 years, male	4 years	Bachelor's degree
14	33 years, male	8 years	Bachelor's degree
15	32 years, male	8 years	Bachelor's degree
16	52 years, male	31 years	Diploma
17	40 years, female	16 years	Bachelor's degree

Thematic analysis revealed five core themes capturing the multifaceted impact of the ECP model on nursing practice, patient care, and interprofessional dynamics:

1. Deepening the nurse-patient connection
2. Empowerment and professional identity growth
3. Streamlining care through organizational innovation
4. Fostering communication and team synergy
5. Navigating challenges and overcoming barriers

Although themes represent shared patterns across participants, the analysis remained grounded in individual accounts, with attention to how each nurse made sense of their experience within the ECP model, in line with IPA principles. Each theme, which is divided into two subthemes (see Figure 1), provides key insights supported by participants' direct quotes, illustrating authentic voices and experiences.

Deepening the nurse-patient connection

This theme captures how participants experienced a transformation in the relational dimension of care, moving beyond task-oriented interactions toward more meaningful engagement. Two sub-themes were identified, reflecting both the structural conditions enabling connection and the emotional processes through which care is interpreted.

Experiencing relational depth in care encounters

For several participants, the ECP model was experienced as enabling a shift from fragmented, task-oriented interactions toward more relational and person-centered encounters. This

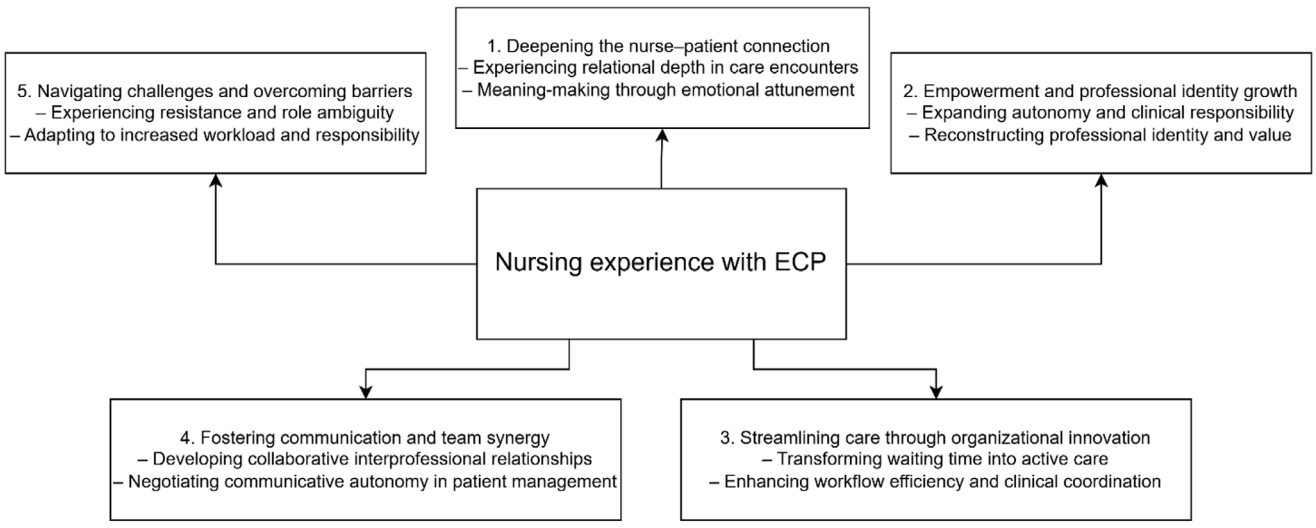


Figure 1. Themes and sub-themes.

transformation was closely tied to the availability of uninterrupted time, which allowed nurses to engage more meaningfully with patients and reframe care as a shared relational process. One participant emphasized how *"applying the ECP means spending meaningful time with the patient, explaining the care pathway, and responding to their needs. This fundamentally increases the patient's feeling of being truly cared for"* (Interview 15), highlighting how time becomes a vehicle for connection rather than merely a logistical resource. Similarly, another nurse reflected that *"having dedicated time and space ensures privacy and genuine care"* (Interview 9), suggesting a reorientation from efficiency-driven care toward relational presence. Through these accounts, care is interpreted not simply as intervention but as a co-constructed relational experience grounded in attention, communication, and mutual recognition. While this experience was shared across participants, the intensity and meaning attributed to relational engagement varied, reflecting individual ways of interpreting care encounters.

Meaning-making through emotional attunement

Beyond the structural availability of time, participants described a deeper emotional engagement with patients, interpreting this as central to their professional role. Emotional attunement emerged as a process through which nurses actively made sense of patients' experiences and responded in a sensitive and individualized manner. As one participant explained, *"listening deeply helps me step into the patient's shoes, understand their emotions, and respond sensitively"* (Interview 16), illustrating how empathy is enacted as an interpretative practice. This was reinforced by another nurse who noted that *"you understand how important it is for the patient to be heard, even in the emergency context. This model allows that"* (Interview 1), emphasizing the value of recognition and voice. Patients' reactions further shaped this meaning-making process, as nurses observed that *"patients seem more composed and more willing to accept waiting times, knowing they are being cared for"* (Interview 10). In this sense, emotional attunement becomes a reciprocal process, through which nurses construct care as both affective and relationally responsive. However, the degree to which autonomy was embraced differed among participants, with some expressing confidence and others highlighting initial uncertainty.

Empowerment and professional identity growth

This theme reflects how the ECP model influenced participants' sense of autonomy, responsibility, and professional self-perception. The analysis revealed two interconnected sub-themes, highlighting both the expansion of clinical agency and the reconstruction of professional identity.

Expanding autonomy and clinical responsibility

Participants consistently interpreted the ECP model as fostering greater autonomy and clinical responsibility, fundamentally reshaping their engagement with care processes. The ability to initiate interventions and make decisions independently was experienced as both empowering and transformative. One nurse described how the model *"boosts self-esteem and awareness of our contribution… it challenges us to be true protagonists in health promotion"* (Interview 3), suggesting that autonomy is internalized as a core dimension of professional identity. This shift was also reflected in interprofessional dynamics, as participants noted that *"communication with physicians improved, and we gained more autonomy in care decisions"* (Interview 15), indicating a redistribution of decision-making authority. Moreover, acting directly on clinical protocols reinforced this sense of agency, as another nurse explained that *"if a patient fits the analgesia protocol, I can administer pain relief immediately"* (Interview 11), highlighting the immediacy of decision-making. *"You feel you are no longer just executing orders, but actively contributing to patient outcomes"* (Interview 6). These experiences highlight how autonomy is not merely granted but actively enacted and embodied in practice, contributing to a sense of professional empowerment. Nevertheless, participants varied in their comfort with this increased autonomy, with some embracing it as empowering and others experiencing it as a source of initial uncertainty.

Reconstructing professional identity and value

Alongside increased autonomy, participants described a broader process of reconfiguring their professional identity, shaped by recognition, responsibility, and visibility within the healthcare team. Nurses interpreted the ECP model as legitimizing their competencies and redefining their role beyond traditional expectations. This was evident in reflections such as *"after implementing the model, we felt our profession finally acknowledged and valued"* (Interview 13), which point to a shift in perceived professional worth. Similarly, the recognition of expanded competencies led one participant to observe that *"nursing is achieving decision-making autonomy previously unrecognized"* (Interview 10), indicating a redefinition of role boundaries. This transformation was also experienced at a personal level, as another nurse noted, *"I feel more competent and responsible, and this model has given me the tools to express my skills more fully"* (Interview 4). Through these accounts, professional identity emerges as fluid and continuously reconstructed, shaped by evolving practices and relational validation. These shifts in professional identity were not experienced uniformly, as participants differed in the extent to which they internalized recognition and redefined their role within the team.

Streamlining care through organizational innovation

This theme explores how participants interpreted changes in workflow and care delivery following the implementation of the ECP model. Two sub-themes were identified, capturing the transformation of time into an active resource and the reorganization of clinical processes.

Transforming waiting time into active care

Participants described a significant shift in how waiting time was experienced within the emergency department, interpreting it no longer as passive delay but as an opportunity for proactive intervention. The ECP model enabled nurses to reframe waiting as *"active waiting",* where care begins earlier and patients are no longer left unattended. This transformation was captured in the observation that *"the ED experience is more efficient; waiting becomes productive care time"* (Interview 3), emphasizing the operational and experiential shift. Participants also highlighted the relational implications of this change, noting that *"patients seem more composed and more willing to accept waiting times, knowing they are being cared for"* (Interview 10). The value of early intervention was further reflected in statements such as *"it's rewarding when a patient comes back just to thank you for relieving their pain promptly"* (Interview 5), indicating the tangible impact on patient experience. *"Even if they wait, they feel something is being done for them"* (Interview 9). In this sense, waiting time is reinterpreted as clinically and relationally meaningful time. Despite this shared perception, participants attributed different meanings to this transformation, with some focusing on efficiency and others emphasizing its impact on patient reassurance and relational care.

Enhancing workflow efficiency and clinical coordination

Participants also emphasized improvements in workflow efficiency and coordination, interpreting the ECP model as enabling a more structured and coherent organization of care. The introduction of dedicated spaces and protocols facilitated concentration and reduced fragmentation, as reflected in the statement *"finally, we have a space to concentrate on reassessment without distractions"* (Interview 15). Early initiation of care was perceived as improving overall flow, with one participant noting that *"starting care earlier saves time and confusion – it's a real game-changer"* (Interview 14). These changes were also experienced as enhancing clarity and predictability in clinical processes. *"Everything is more organized, and you know what to do sooner"* (Interview 2). *"It reduces the chaos that usually characterizes the emergency department"* (Interview 6). These experiences suggest that organizational innovation not only improves efficiency but also reshapes how nurses perceive and manage clinical complexity. However, the perceived benefits of organizational changes varied among participants, reflecting individual ways of adapting to and making sense of new workflows.

Fostering communication and team synergy

This theme illustrates how the ECP model reshaped communication practices and interprofessional relationships within the emergency department. The analysis identified two sub-themes, reflecting both the development of collaborative dynamics and the emergence of communicative autonomy.

Developing collaborative interprofessional relationships

Participants described a shift toward more collaborative relationships with physicians, interpreting this as a move toward greater professional integration. Communication was experienced as more open and reciprocal, enabling nurses to participate more actively in care decisions. One nurse reflected that *"There's more dialogue now; physicians listen and truly work with us to manage care"* (Interview 2), illustrating a change in relational dynamics. This collaborative approach was also linked to patient safety, as another participant emphasized that *"Communication among us is key to maintaining patient safety"* (Interview 7). *"We are more aligned as a team, and this improves how we work together"* (Interview 12). These accounts suggest a reconfiguration of professional relationships, grounded in mutual respect and shared responsibility. At the same time, participants differed in how they experienced these changes, with some describing strong collaboration and others highlighting ongoing tensions within the team.

Negotiating communicative autonomy in patient management

In parallel, participants described increased autonomy in communicating with patients and managing initial care decisions. This shift allowed nurses to take a more proactive role in guiding patients through their care pathway. As one participant stated, *"We answer patient questions and decide independently, without always referring to physicians"* (Interview 6), highlighting reduced dependency on physicians. The model also enabled greater involvement in patient education, expanding the communicative dimension of care. *"Now I explain the process directly to the patient, and they rely on me"* (Interview 8). *"We also have more time to provide information, which patients really appreciate"* (Interview 5). Communication thus becomes a space of autonomy and responsibility, reinforcing the expanded scope of nursing practice. This increased communicative autonomy was interpreted differently across participants, depending on their confidence, experience, and prior role expectations.

Navigating challenges and overcoming barriers

This theme addresses the difficulties and tensions encountered during the implementation of the ECP model. Two sub-themes were identified, highlighting both the experience of resistance and ambiguity, and the process of adaptation to increased demands.

Experiencing resistance and role ambiguity

Despite the positive aspects of the ECP model, participants described challenges related to resistance from physicians and unclear role boundaries. These tensions were interpreted as part of a broader process of change, where established roles were being renegotiated. One nurse expressed frustration, stating that *"sometimes I have to push physicians to take over patients I initially saw, which can be frustrating"* (Interview 3), highlighting difficulties in interprofessional collaboration. Uncertainty about roles was also evident, as participants described ambiguity in responsibilities. *"At the beginning, it wasn't clear where our role ended and the physician's began"* (Interview 14). *"Some colleagues were skeptical and didn't trust the model at first"* (Interview 12). These experiences reflect the complexity and tension inherent in organizational transformation. The experience of resistance was not uniform, as some participants perceived it as a significant barrier, while others interpreted it as part of a natural process of organizational change.

Adapting to increased workload and responsibility

Participants also described the increased workload and responsibility associated with the ECP model, particularly during its initial implementation. Managing new protocols

alongside existing duties was experienced as demanding, as one nurse explained that *"learning new protocols while managing existing duties was demanding"* (Interview 7). Initial hesitation and concern were also present, as reflected in the statement *"I hesitated, worried it would interfere with my core tasks"* (Interview 17). However, over time, participants described a process of adaptation and growing confidence. *"At first it felt overwhelming, but then it became part of the routine"* (Interview 8). *"Now I feel more confident, even if the responsibility is greater"* (Interview 4). These accounts illustrate how challenges are integrated into a process of professional development and adaptation, rather than remaining purely as obstacles. Over time, participants made sense of these challenges in different ways, with some integrating them into professional growth and others continuing to perceive them as ongoing strain.

Discussion

From an interpretative phenomenological perspective, these findings suggest that the ECP model is not merely an organizational innovation but represents a transformative experiential shift in how nurses understand and enact their professional role. Participants' accounts indicate a reconfiguration of meaning across relational, professional, and organizational dimensions, highlighting the dynamic interplay between autonomy, responsibility, and identity construction. From a phenomenological perspective, these findings can be understood as reflecting a process of meaning-making in which nurses actively reinterpret their role within a changing clinical environment. The ECP model appears not only to modify organizational practices but also to reshape how nurses experience their professional identity and relational engagement with patients.

This study provides an important and timely contribution to the growing body of literature on innovative nursing care models in emergency settings, focusing particularly on the Italian healthcare system. Utilizing an IPA approach, the research offers an in-depth exploration of the lived experiences of nurses engaged in the implementation of the ECP model. The rich qualitative data not only illuminate clinical and organizational changes but also highlight the emotional, relational, and professional impacts on nursing practice. By centering the perspectives of emergency nurses – often underrepresented in healthcare policy and system reform discussions – this study elucidates the complex interactions between advanced nursing roles, care delivery processes, and interdisciplinary collaboration.

The findings reveal that the ECP model significantly contributes to nurse empowerment and professional development. Participants consistently reported increased autonomy, expanded clinical responsibilities, and enhanced visibility within multidisciplinary teams. This evolving professional identity was characterized by greater self-esteem, reinforced clinical authority, and a stronger sense of ownership in patient care decisions. The ability to initiate protocols and administer medications independently led many nurses to view themselves as "protagonists of health and prevention". These results align with contemporary research on Advanced Practice Nurses (APNs), which shows that autonomous application of evidence-based protocols enhances nurse engagement, motivation, and professional satisfaction (Lenza et al., 2023). However, empowerment was not uniformly experienced. Some participants identified barriers including role ambiguity, skepticism, and hesitation to assume new responsibilities, underscoring the necessity for ongoing organizational support, clear role definitions, and tailored training programs. Empowerment should thus be understood as a dynamic and context-dependent process rather than a fixed state (Gawthorne et al., 2025). These findings can be interpreted as a process of professional identity reconstruction, in which autonomy and responsibility are not merely functional changes but are integrated into nurses' self-understanding. From this perspective, the ECP model contributes to redefining nursing as an active, decision-making profession, rather than a task-oriented role.

From an organizational perspective, the ECP model contributed to the restructuring of traditional hierarchies, fostering greater collaboration and parity between nurses and physicians. Participants described a shift toward shared decision-making and a more horizontal model of care delivery. This interdisciplinary synergy is critical in high-acuity environments, where effective communication and mutual trust enhance both team cohesion and patient

safety (Mota et al., 2024). At a broader level, these changes can be interpreted as a shift toward more collaborative and less hierarchical models of care, in which professional boundaries become more fluid. This transformation reflects an ongoing reconfiguration of interprofessional roles, where meaning is negotiated through interaction and shared clinical responsibility.

Additionally, the introduction of early care protocols improved workflow efficiency by transforming waiting times into periods of active intervention. Early analgesia administration and timely reassessment reduced delays and facilitated faster access to diagnostic pathways (Interview 11), consistent with studies on nurse-led fast-track protocols demonstrating improved patient throughput and reduced ED length of stay (Curtis et al., 2023; Fournier et al., 2026). The establishment of dedicated reassessment areas further optimized resource utilization and reinforced continuity of care, promoting interdisciplinary coordination (Benjamin, 2025). Nurses also reported a more positive work environment characterized by improved communication and mutual respect with physicians, indicating that such models not only enhance patient flow but also reshape team dynamics toward shared responsibility and collaborative problem-solving (Mota et al., 2024; Ruiz, 2020).

Participants consistently emphasized that the ECP model enabled more authentic and individualized patient care by providing dedicated time and clinical autonomy. This enhanced the nurse-patient relationship through increased trust, active listening, and emotionally attuned care. Nurses described this experience as enabling "true care" (O'Hagan et al., 2014), which aligns with patient-centered care literature highlighting the importance of quality communication and relational continuity in reducing patient anxiety, improving adherence, and enhancing health outcomes (Walsh et al., 2022). Nurses also observed greater patient calmness and satisfaction when preliminary nursing care preceded physician evaluation (MacIsaac & Peter, 2025). Such relational benefits are particularly valuable in overcrowded and high-stress emergency settings, where emotional reassurance and clear information significantly influence patient perceptions of care quality (MacIsaac & Peter, 2025). From a phenomenological perspective, the enhanced nurse–patient relationship described by participants can be understood as a re-centering of care on the lived experience of the patient. This suggests that relational care is not an additional component of practice but a fundamental dimension through which clinical work acquires meaning.

Despite these positive effects, the implementation of the ECP model faced challenges. Some participants expressed initial resistance due to skepticism, uncertainty regarding evolving roles, and discomfort with increased responsibilities. These barriers highlight the importance of sustained leadership engagement, continuous professional development, and clear communication to facilitate role clarity and acceptance. Without such supports, the relational and organizational benefits may be unevenly distributed and difficult to maintain over time (Gawthorne et al., 2025). These challenges can be interpreted not only as organizational barriers but also as moments of tension within the process of professional transformation. Resistance, uncertainty, and adaptation reflect the complexity of integrating new meanings into established practices.

Overall, the findings suggest that the implementation of the ECP model represents not only a structural innovation but a transformation in how nurses interpret, experience, and give meaning to their role within emergency care. Beyond its contextual relevance, this study offers a conceptual contribution by illuminating how nurses interpret and give meaning to organizational innovation within emergency care. The findings suggest that the implementation of the ECP model is not only a structural change but also a process of professional and relational transformation, in which autonomy, identity, and care practices are actively redefined. This study contributes to the existing literature by extending current understandings of nurse-led models beyond efficiency outcomes, highlighting the experiential and meaning-making dimensions of practice. In this sense, the findings offer insights that may be transferable to other healthcare contexts where similar organizational innovations aim to expand nursing roles and enhance patient-centered care.

This study presents several limitations that must be considered when interpreting the findings. First, the sample was limited to 17 nurses from a single ED in Northern Italy. While appropriate for an IPA approach, this narrow

scope may have constrained the diversity of perspectives and limited the transferability of the results to other healthcare contexts, including within the Italian setting where healthcare organization may vary across regions. Moreover, despite efforts to recruit a heterogeneous sample, differences in age, education, and professional experience among participants may have influenced their perceptions. The implementation of the ECP model also faced organizational challenges, including resistance to change, unclear procedural guidelines, and inconsistent adherence to protocols, which may have impacted its overall effectiveness (Interview 3, 7, 12). Importantly, the study did not include the viewpoints of other key stakeholders such as physicians, administrators, or patients. The absence of these perspectives limits the comprehensiveness of the analysis and understanding of the model's systemic impact.

In addition, as with all qualitative interpretative research, the findings are inevitably shaped by the researchers' role in the analytic process. Although reflexive strategies were employed, including bracketing and team discussions, the interpretation of participants' experiences is influenced by the researchers' perspectives and professional backgrounds. Furthermore, the translation of data from Italian to English represents a potential limitation. Although careful procedures were followed to preserve semantic accuracy, nuances of meaning embedded in the original language may not be fully transferable. As meaning in qualitative research is closely tied to language, this process may have influenced the interpretation of participants' narratives.

Implications for Practice

The findings demonstrate that nurse-led protocols embedded in the ECP model have the potential to enhance the quality, timeliness, and continuity of emergency care by strengthening nurses' autonomy, clinical reasoning, and decision-making capabilities. Clinically, the model supports optimizing patient flow while fostering the relational aspects of care, such as trust and emotional support, which are often compromised in crowded ED settings. Organizationally, the study highlights the importance of revising workflows and professional roles to encourage interdisciplinary collaboration and shared responsibility. However, successful implementation requires strong leadership, ongoing professional development, and inclusive change management to overcome resistance, role ambiguity, and uneven training.

Future Perspectives

Future research should adopt a multi-stakeholder approach to better capture the diverse experiences of nurses, physicians, administrators, and patients, thereby providing a more comprehensive evaluation of the ECP model's feasibility and impact. Incorporating patient perspectives would deepen understanding of the emotional and relational dimensions of early care, while mixed-methods studies could quantify clinical outcomes such as ED length of stay, time to analgesia, patient satisfaction, and continuity of care post-discharge. Moreover, the development and validation of tools to measure constructs like perceived nurse autonomy, therapeutic alliance, and emotional climate would enable systematic assessment of the model's effects on care delivery, professional satisfaction, and organizational efficiency. Given the ongoing challenge of ED overcrowding, refining and scaling nurse-led protocols such as the ECP represents a strategic priority to improve patient outcomes and system efficiency.

Conclusion

This study contributes valuable insights into the implementation and impact of the ECP model within a high-pressure ED context. By focusing on nurses' experiences, the research highlights the critical role of nurse-led protocols in enhancing clinical autonomy, decision-making, and relational care. The findings emphasize how empowering nurses through structured, evidence-based frameworks can improve patient flow, reduce delays, and foster a more patient-centered approach, even in overcrowded and resource-constrained settings.

However, the study also underscores the complexity of integrating such innovations into real-world clinical practice. Organizational barriers, including resistance to change, unclear

guidelines, and variable adherence, can hinder effective implementation. Overcoming these challenges requires strong leadership, targeted training, and inclusive strategies that promote interdisciplinary collaboration and shared responsibility. Recognizing nurses as both technical experts and relational professionals is essential for advancing emergency care quality and sustainability.

Looking ahead, this research lays the groundwork for further exploration of nurse-led models across diverse healthcare environments. Future studies incorporating multi-stakeholder perspectives and mixed methods will be crucial to validate and scale the ECP approach. Ultimately, fostering professional transformation and system innovation through nurse empowerment represents a promising path to meet the evolving demands of emergency healthcare and improve patient outcomes. By providing an interpretative account of nurses' lived experiences, this study advances current knowledge on the role of meaning-making in the successful implementation of innovative care models.

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Original Research

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Self-Care Behaviors and Quality of Life in Inflammatory Bowel Disease Patients: A Multicentre Study

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Abstract

Introduction. Health-related quality of life (HRQoL) is substantially impaired in individuals living with inflammatory bowel disease (IBD). Although self-care is considered a key component of chronic disease management, the specific contributions of different self-care dimensions to physical and mental HRQoL remain poorly understood. This study examined the relationship between self-care behaviours and HRQoL in patients with IBD.

Methods. A multicentre cross-sectional study was conducted among 453 adult patients with Crohn's disease or ulcerative colitis recruited from outpatient IBD centres in Italy. Self-care

was assessed using the Self-Care of Chronic Illness Inventory (SC-CII), and HRQoL was measured using the 12-Item Short Form Health Survey (SF-12). Generalized Additive Models (GAMs) adjusted through Directed Acyclic Graph (DAG)-informed confounding control were used to investigate linear and nonlinear associations between self-care dimensions and HRQoL.

Results. Self-care monitoring showed the highest mean score, whereas self-care maintenance and management were below the established adequacy threshold. No significant associations emerged between self-care dimensions and mental HRQoL. A weak nonlinear association was observed between self-care management and physical HRQoL, suggesting that higher management behaviours may reflect increased disease burden rather than better health status. Overall model fit was limited (adjusted $R^2 = 0.024$ for PCS-12 and −0.002 for MCS-12), indicating that self-care explained only a small proportion of HRQoL variability.

Discussion. The findings suggest that self-care behaviours alone may not fully explain variations in HRQoL among patients with IBD. Physical and mental well-being appear to be influenced by a complex interplay of clinical, psychological, and behavioural factors. Future longitudinal studies should explore the role of psychosocial determinants and causal pathways linking self-care and quality of life.

Keyword: Inflammatory Bowel Disease, Self-Care, Quality of Life, Nursing, Chronic Disease, Patient-Reported Outcome

Introduction

Inflammatory bowel disease (IBD), encompassing Crohn's disease (CD) and ulcerative colitis (UC), is a chronic relapsing-remitting condition with a substantial and growing global burden. The prevalence of IBD exceeds 0.3% in North America, Oceania, and many European countries, with the highest reported values reaching 505 per 100,000 for UC in Norway and 322 per 100,000 for CD in Germany (Ng et al., 2017). In 2019, approximately 4.9 million cases were estimated worldwide, with incidence rising rapidly in newly industrialized regions (Wang et al., 2025). The prevalence in the Western world is projected to reach 1% by 2030, potentially affecting 10 million individuals (Kaplan & Windsor, 2021).

IBD significantly impairs health-related quality of life (HRQoL) across physical, psychological, and social domains (Casellas et al., 2001; Knowles et al., 2018). This impairment is most pronounced during active disease, whereas clinical remission is associated with HRQoL levels approaching general-population norms. Psychological factors, particularly depression and anxiety, are among the strongest determinants of poor HRQoL, often exerting effects independent of, and sometimes exceeding, those of physical symptoms (Thomann et al., 2023; Zhang et al., 2013). Additional contributors include maladaptive coping, visceral sensitivity, illness identity, and food-related distress, which interact with inflammatory burden to further compromise nutritional status and social participation (Almarzouki et al., 2024; Whelan et al., 2021).

The Middle-Range Theory of Self-Care of Chronic Illness conceptualizes self-care as a dynamic process comprising three distinct but interrelated dimensions (Riegel et al., 2012): self-care maintenance, referring to

behaviours aimed at maintaining health and disease stability (e.g., adhering to prescribed medication, maintaining an appropriate diet, and engaging in regular physical activity); self-care monitoring, involving the observation and recognition of changes in signs and symptoms (e.g., monitoring stool frequency, rectal bleeding, abdominal pain, or bowel urgency); and self-care management, referring to actions taken in response to symptoms when they occur (e.g., contacting the IBD care team when symptoms worsen, seeking timely clinical assessment, or implementing previously agreed symptom-management strategies). Within this theoretical framework, these dimensions represent complementary components of the self-care process and may relate differently to clinical and patient-reported outcomes.

The relationship between self-care and health-related quality of life (HRQoL) in chronic illnesses is well established in the literature. Higher levels of self-care, particularly self-care maintenance, are consistently associated with significant improvements in both physical and mental HRQoL, whereas self-care monitoring and self-care management appear to show weaker or context-dependent associations (Cai et al., 2025; Kim et al., 2026). This relationship is mediated by factors such as self-efficacy and self-care confidence, which influence the overall self-care process and, consequently, clinical outcomes (Chin et al., 2021; Peters et al., 2019).

Self-care capacity in IBD is influenced by multiple psychological, personal, and relational factors. Higher self-efficacy, health literacy, resilience, and nurse-patient mutuality are associated with better self-care behaviours and improved disease outcomes, whereas health anxiety and greater disease severity negatively affect self-care capacity (Napolitano, Bassola, et al., 2026; Napolitano, Bozzetti, et al., 2025; Napolitano, Cilluffo, Marini, et al., 2025; Papp-Zipernovszky et al., 2026; Sheehan et al., 2024; Stone et al., 2022). Overall, current evidence supports an integrated theoretical approach to understanding self-care in IBD (Napolitano, Bozzetti, et al., 2026).

Despite growing evidence linking self-care to HRQoL, the mechanisms through which different self-care dimensions influence patient-reported outcomes remain insufficiently understood. Low levels of self-care, health literacy, and self-care agency are consistently associated with poorer HRQoL (Hu & Xu, 2024; Lovén Wickman et al., 2019; Napolitano, Biagioli, et al., 2025).

Mediation analyses indicate that self-care and health literacy independently and sequentially mediate the relationship between psychological distress and HRQoL, suggesting that self-care deficits directly contribute to worse outcomes (Hu & Xu, 2024; Tormey et al., 2019).

However, most existing studies rely on descriptive or correlational designs, and robust predictive models testing self-care as a direct determinant of HRQoL are scarce (Barello et al., 2021; Demers et al., 2025). In particular, the independent contribution of self-care maintenance, monitoring, and management to physical and mental HRQoL remains underexplored, and previous investigations have predominantly employed linear analytical approaches, potentially overlooking complex nonlinear associations.

Aim

The aim of this study is to examine the associations between the different dimensions of self-care and physical and mental HRQoL in patients with IBD.

Methods

Study design

A multicentre, observational, cross-sectional study was conducted as a secondary analysis of baseline data from the multicentre longitudinal IBD-SELF study (Napolitano et al., 2024). Reporting adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional studies (von Elm et al., 2008).

Ethical Considerations

The study was conducted in accordance with Good Clinical Practice and the Revised Declaration of Helsinki. The Territorial Ethics Committee (Lazio 3) reviewed and approved the protocol (Approval No. 0023486/23, dated August 2, 2023). Before enrollment, all participants received detailed oral and written information regarding the study's objectives and procedures and provided written informed consent.

Study size

This study represents a secondary analysis of data collected within the IBD-SELF study, whose protocol and sample size determination have been previously published (Napolitano et al., 2024). The parent study planned to recruit at least 250 patients with IBD. The original sample size was based on an approximately 10:1 ratio between cases and model parameters, with 200 participants considered sufficient to achieve 80% power for a moderate effect size (0.4). For the present secondary analysis, all eligible patients with complete data available for the variables of interest were included, resulting in a final analytic sample of 453 participants.

Participants and setting

Consecutive adult patients were recruited from outpatient IBD units across northern, central, and southern Italy to enhance geographic representativeness. Eligibility criteria included: age ≥18 years, a confirmed diagnosis of CD or UC, the ability to read and understand Italian, and written informed consent. Exclusion criteria were: diagnosis within the previous 12 months, IBD-related surgery within the previous 6 months, presence of another severe symptomatic chronic disease, and cognitive impairment precluding questionnaire completion. Participants were enrolled during routine outpatient visits by trained IBD nurses.

Measures

Health-related quality of life

HRQoL was assessed using the 12-Item Short Form Health Survey (SF-12), a widely validated instrument derived from the SF-36 (Ware et al., 1996). Two summary scores were computed: the Physical Component Summary (PCS-12) and the Mental Component Summary (MCS-12). Both scores are norm-based, standardised to a mean of 50 and a standard deviation of 10 in the general US population, with higher scores indicating better perceived health (Jakobsson et al., 2012; Ware et al., 1996). The SF-12 has been previously used to assess generic HRQoL in IBD populations (Tiles-Sar et al., 2025)

Self-care

Self-care was evaluated using the Self-Care of Chronic Illness Inventory (SC-CII), a theory-based tool grounded in the Middle-Range Theory of Self-Care for Chronic Illness. The SC-CII assesses three scales: self-care maintenance, self-care monitoring, and self-care management—each rated on a standardized 0–100 scale, with higher scores indicating better self-care and a cutoff of 70 signifying adequate levels (Vellone, Lorini, et al., 2020). The instrument has demonstrated strong reliability and construct validity across diverse chronic disease populations (Ling et al., 2021; Riegel et al., 2018; Vellone, Barbaranelli, et al., 2020) and has been specifically validated in patients with IBD, confirming its factorial validity and internal consistency (Napolitano, Biagioli, et al., 2025).

Sociodemographic and clinical variables

Sociodemographic and clinical characteristics were collected to describe the study population and to adjust for potential confounding in multivariable analyses. Age and years since diagnosis were treated as continuous variables. Sex was coded as male or female. Educational level was categorised into four groups: primary school, middle school, high school, and bachelor's degree or higher. IBD type was recorded as CD or UC. Disease activity was classified as remission, mild, moderate, or severe, based on validated clinical indices routinely used in outpatient care: the Harvey-Bradshaw Index (HBI) for CD and the Mayo Score for UC (Harvey & Bradshaw, 1980; Lewis et al., 2008).

The HBI is a simplified clinical index based on five variables (general well-being, abdominal pain severity, number of liquid stools daily, abdominal mass, and complications), with scores ≤4 indicating remission. The Mayo Score assesses stool frequency, rectal bleeding, mucosal appearance at endoscopy, and the physician's global assessment, with lower scores indicating less active disease. Smoking status was recorded as non-smoker, former smoker, or current smoker. All clinical variables were retrieved from medical records at the time of the outpatient visit, ensuring temporal alignment between patient-reported and clinical data.

Statistical Analysis

Analyses were performed using R, version 4.5.0 (R Core Team, 2023). The relationship between SC-CII Maintenance, Monitoring, and Management and patients' HRQoL (SF-12 Physical Component Summary [PCS-12] and Mental Component Summary [MCS-12]) was investigated through Generalized Additive Models (GAMs) using the *mgcv* package. GAMs are a flexible extension of the Generalized Linear Model (GLM) framework that allow nonlinear relationships between predictors and outcomes to be estimated through smooth functions (smooth splines). Unlike linear models, which assume a constant rate of change across the range of the predictor, GAMs approximate complex, potentially curvilinear associations without pre-specifying their functional form. This flexibility is particularly useful in psychosocial and clinical research, where effects may not be linear—for instance, incremental increases in self-care behaviours may be associated with HRQoL only up to a saturation point, beyond which further increases may have minimal or different effects. Formally, a GAM models the expected value of the outcome Y as:

$$g\,(E[Y]) = \beta_0 + s_1(X_1) + s_2(X_2) + \ldots\ldots + \varepsilon$$

where g is a link function (identity in our case), and $s_i(X_i)$ are smooth functions estimated by penalized regression splines. The degree of smoothness is selected automatically by Restricted Maximum Likelihood (REML), balancing goodness of fit and model parsimony to prevent overfitting. Although Structural Equation Modeling (SEM) could also capture latent constructs and interrelations between variables, it requires the specification of linear relationships and a predefined causal structure. Given our interest in detecting potential nonlinear associations between specific observed measures (SC-CII subscales and SF-12 scores), GAMs provided a more robust and data-driven alternative. In contrast to SEM, GAMs do not rely on multivariate normality, are less sensitive to small-sample misspecification, and can flexibly model non-linear effects even with limited sample size, provided penalization is applied. Potential confounding was examined using Directed Acyclic Graphs (DAGs) constructed with the *dagitty* package in R (Textor et al., 2011).

DAGs are graphical representations of hypothesized causal relationships between variables, where nodes represent variables and arrows represent directed causal effects. They are acyclic, meaning that no variable can causally influence itself through a feedback loop. DAG-based causal reasoning identifies which variables need to be statistically controlled (the minimal sufficient adjustment set) to obtain an unbiased estimate of the exposure–outcome relationship. In the present study, the DAG was specified to reflect theoretical and empirical knowledge on self-care and quality of life in IBD patients. Sociodemographic characteristics (age, gender, education) and disease-related variables (pathology, disease activity, years since diagnosis, and smoking status) were assumed to influence both self-care (SC-CII scales) and HRQoL, and were therefore modelled as potential confounders. Based on this causal structure, the dagitty analysis identified a minimal sufficient adjustment set comprising age, gender, education, pathology, disease activity, years since diagnosis, and smoking status. All GAMs estimating the associations between SC-CII subscales and SF-12 (PCS-12 and MCS-12) outcomes were accordingly adjusted for this set to approximate the total association under the assumed causal model.

Results

A total of 453 patients were included in the analyses. Descriptive statistics for all study variables are presented in Table 1. The sample was balanced by sex (49.0% female, 51.0% male) and IBD type (49.2% CD, 50.8% UC). Mean age was 43.85 years (SD = 16.28), and mean disease duration was 11.64 years (SD = 9.37). The majority of participants were in clinical remission (57.2%), while 15.5% had mild, 15.5% moderate, and 11.9% severe disease activity. Regarding education, 44.6% had completed high school and 32.5% held a bachelor's degree or higher.

Mean HRQoL scores were 45.95 (SD = 5.62) for PCS-12 and 37.05 (SD = 8.66) for MCS-12, indicating physical health slightly below the general population norm (50) and substantially impaired mental health. Mean SC-CII scores were 69.75 (SD = 11.33) for maintenance, 80.59 (SD = 17.63) for monitoring, and 68.79 (SD = 16.75) for management. Using the established adequacy threshold of ≥70 (Vellone, Barbaranelli, et al., 2020), mean maintenance

and management scores fell below the cutoff, while monitoring exceeded it.

Table 1. Descriptive statistics for study variables.

Variable	Values
HRQoL, M (SD)	
PCS-12	45.95 (5.62)
MCS-12	37.05 (8.66)
SC-CII scales, M (SD)	
SC-CII Maintenance	69.75 (11.33)
SC-CII Monitoring	80.59 (17.63)
SC-CII Management	68.79 (16.75)
Age (years), M (SD)	43.85 (16.28)
Years since diagnosis, M (SD)	11.64 (9.37)
Sex, n (%)	
Female	222 (49.0%)
Male	231 (51.0%)
Education, n (%)	
Bachelor's degree or higher	147 (32.5%)
Primary school	15 (3.3%)
High school	202 (44.6%)
Middle school	89 (19.6%)
IBD type, n (%)	
Crohn's disease	223 (49.2%)
Ulcerative colitis	230 (50.8%)
Disease activity, n (%)	
Mild	70 (15.5%)
Moderate	70 (15.5%)
Remission	259 (57.2%)
Severe	54 (11.9%)
Smoking status, n (%)	
Former smoker	125 (27.6%)
Non-smoker	230 (50.8%)
Current smoker	98 (21.6%)

Note. HRQoL = health-related quality of life; PCS-12 = Physical Component Summary of the 12-Item Short Form Health Survey; MCS-12 = Mental Component Summary; SC-CII = Self-Care of Chronic Illness Inventory; IBD = inflammatory bowel disease. Values are reported as mean (standard deviation) for continuous variables and number (percentage) for categorical variables. Percentages may not sum to exactly 100% due to rounding.

Association Between Health-Related Quality of Life and SC-CII

Physical Health-related quality of life (PCS-12)

In DAG-adjusted GAMs (Table 2), SC-CII Management showed a statistically significant nonlinear association with PCS-12 (edf = 3.09; F = 2.73; p = 0.035). No evidence of association was observed for SC-CII Maintenance (edf = 1.00; p = 0.775) or Monitoring (edf = 1.00; p = 0.833). Overall model fit was weak (adjusted R^2 = 0.024; deviance explained = 6.65%).

Model-based contrasts were consistent with these findings. Moving from the 25th to the 75th percentile of SC-CII Management (60.00 to 80.00) was associated with a decrease in PCS-12 (Δ[75–25] = −1.10; 95% CI −2.24 to 0.04), suggesting a nonlinear pattern in which higher management scores were not uniformly associated with better physical HRQoL. Corresponding contrasts for Maintenance (Δ[75–25] = 0.13; 95% CI −0.78 to 1.05) and Monitoring (Δ[75–25] = 0.09; 95% CI −0.73 to 0.91) were small and non-significant.

Mental Health-Related Quality of Life (MCS-12)

In DAG-adjusted GAMs (Table 3), no SC-CII domain showed a statistically significant association with MCS-12. The smooth terms for Maintenance (edf = 1.37; F = 2.49; p = 0.136), Monitoring (edf = 1.00; F = 0.63; p = 0.428), and Management (edf = 1.00; F = 0.41; p = 0.523) were all non-significant. Overall model fit was poor (adjusted R^2 = −0.002; deviance explained = 3.66%).

Model-based contrasts confirmed these null findings. Moving from the 25th to the 75th percentile of SC-CII Maintenance was associated with a non-significant decrease in MCS-12 (Δ[75–25] = −1.29; 95% CI −2.79 to 0.22). Corresponding contrasts for Monitoring (Δ[75–25] = −0.51; 95% CI −1.78 to 0.75) and Management (Δ[75–25] = 0.34; 95% CI −0.71 to 1.39) were similarly non-significant. Models visualization is depicted in Figure 1.

Mental Health-Related Quality of Life (MCS-12)

In DAG-adjusted GAMs (Table 3), no SC-CII domain showed a statistically significant association with MCS-12. The smooth terms for

Table 2. Generalized additive models for PCS-12.

Associated Term	edf	F	*p*	25th percentile	75th percentile	Δ (75–25)	95% CI lower	95% CI upper
SC-CII Maintenance	1.00	0.08	0.775	60.70	78.60	0.13	−0.78	1.05
SC-CII Monitoring	1.00	0.04	0.833	70.00	95.00	0.09	−0.73	0.91
SC-CII Management	3.09	2.73	0.035	60.00	80.00	−1.10	−2.24	0.04

Note. edf = effective degrees of freedom for the smooth term; F = approximate F statistic for the smooth function. Models were estimated using REML and adjusted for age and years since diagnosis (smooth terms) and for sex, education, IBD type, disease activity, and smoking status (parametric terms). Adjusted R^2 = 0.024; deviance explained = 6.65%.

Maintenance (edf = 1.37; F = 2.49; p = 0.136), Monitoring (edf = 1.00; F = 0.63; p = 0.428), and Management (edf = 1.00; F = 0.41; p = 0.523) were all non-significant. Overall model fit was poor (adjusted R^2 = −0.002; deviance explained = 3.66%).

Model-based contrasts confirmed these null findings. Moving from the 25th to the 75th percentile of SC-CII Maintenance was associated with a non-significant decrease in MCS-12 (Δ[75–25] = −1.29; 95% CI −2.79 to 0.22). Corresponding contrasts for Monitoring (Δ[75–25] = −0.51; 95% CI −1.78 to 0.75) and Management (Δ[75–25] = 0.34; 95% CI −0.71 to 1.39) were similarly non-significant. Models visualization is depicted in Figure 1.

Derivative-based analyses of the SC-CII Maintenance smooth

Given the estimated nonlinearity of the SC-CII Maintenance smooth (edf = 1.37), derivative-based analyses using simultaneous 95% confidence intervals were conducted to further characterize the shape of the association. Across the evaluated domain (Maintenance = 35.71 to 100.00), simultaneous confidence intervals for the first derivative included zero throughout, indicating no statistically supported region of monotonic increase or decrease in MCS-12 associated with Maintenance.

Figure 1 displays the partial effect plots from the DAG-adjusted GAMs. The top row depicts the smooth terms for PCS-12, and the bottom row for MCS-12. Each panel represents the partial effect of a SC-CII subscale on the outcome, adjusted for the minimal sufficient confounding set (age, sex, education, IBD type, disease activity, years since diagnosis, and smoking status). Shaded areas correspond to 95% confidence intervals. The nonlinear association between SC-CII Management and PCS-12 is visually apparent, whereas all other associations are consistent with null effects.

Table 3. Generalized additive models for MCS-12.

Associated Term	edf	F	*p*	25th percentile	75th percentile	Δ (75–25)	95% CI lower	95% CI upper
SC-CII Maintenance	1.37	2.49	0.136	60.70	78.60	−1.29	−2.79	0.22
SC-CII Monitoring	1.00	0.63	0.428	70.00	95.00	−0.51	−1.78	0.75
SC-CII Management	1.00	0.41	0.523	60.00	80.00	0.34	−0.71	1.39

Note. effective degrees of freedom for the smooth term; F = approximate F statistic for the smooth function. Models were estimated using REML and adjusted for age and years since diagnosis (smooth terms) and for sex, education, IBD type, disease activity, and smoking status (parametric terms). Adjusted R^2 = −0.002; deviance explained = 3.66%.

Covariate Associations

Associations between covariates and HRQoL outcomes are reported in Supplementary Tables S1 and S2. No covariate reached statistical significance for either PCS-12 or MCS-12 in the adjusted models, although a trend toward lower PCS-12 was observed for middle school education (estimate = −1.47; SE = 0.83; p = 0.076) and moderate disease activity showed a trend toward higher PCS-12 (estimate = 1.90; SE = 1.03; p = 0.066).

Discussion

This multicentre study examined the relationship between self-care behaviours and

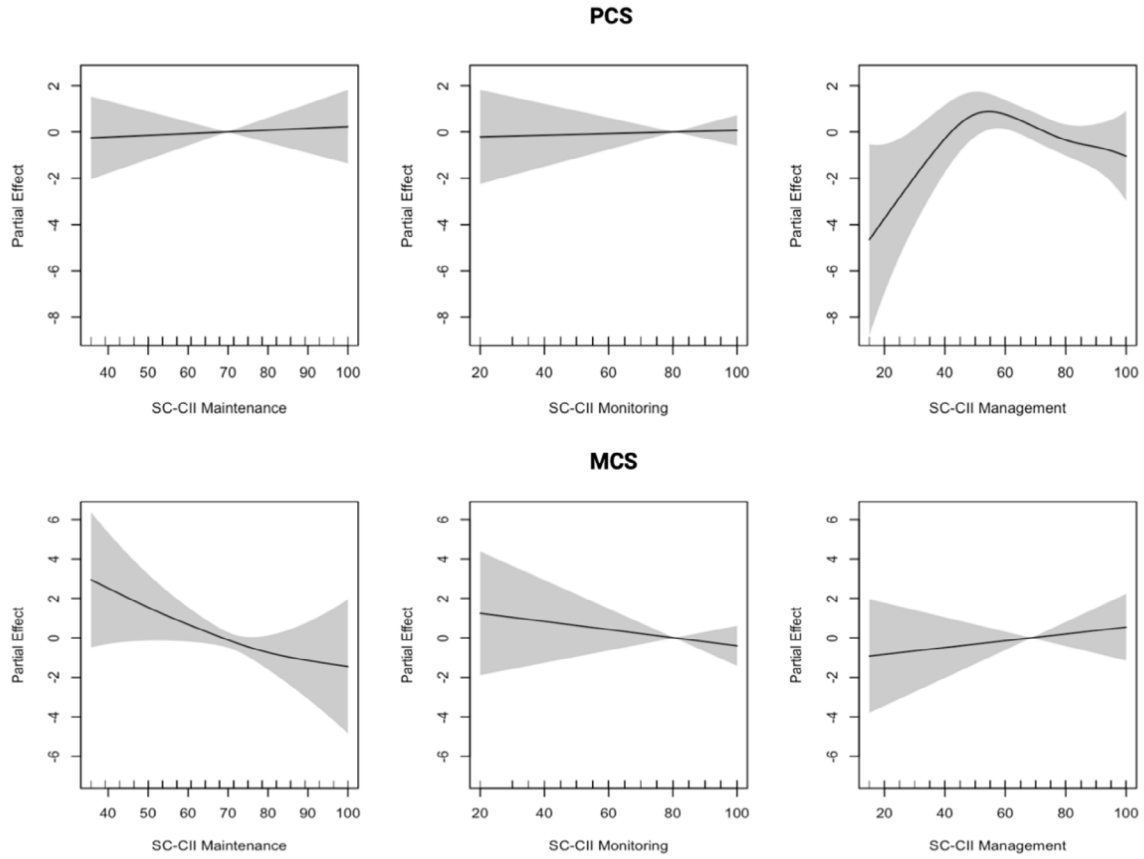


Figure 1. Partial effect plots from GAMs showing the adjusted associations between SC-CII Self-care scales and health-related quality of life outcomes (PCS-12 and MCS-12). The top row displays smooth terms for physical HRQoL (PCS-12), and the bottom row displays smooth terms for mental health (MCS-12). Each panel represents the partial effect of a SC-CII subscale on the outcome, adjusted for the minimal sufficient confounding set identified through the DAG (age, gender, education, pathology, disease activity, years since diagnosis, and smoking status). Shaded areas correspond to 95% confidence intervals. Only the SC-CII Management scale showed a statistically significant non-linear association with PCS-12, whereas no SC-CII scales demonstrated a significant association with MCS-12.

Table S1. Associations between covariates and PCS12.

Covariates	Estimate	Std. Error	p value
Gender (Male)	-0.24	0.57	0.675
Education –Primary school	-1.35	1.73	0.434
Education – High school	0.10	0.66	0.876
Education – Middle school	-1.47	0.83	0.076
Pathology – Colitis	-0.93	0.61	0.131
Disease activity – Moderate	1.90	1.03	0.066
Disease activity – Remission	1.02	0.82	0.214
Disease activity – Severe	-0.08	1.09	0.939
Smoking – Non smoker	0.15	0.70	0.831
Smoking – Smoker	-0.62	0.83	0.456

Table S2. Associations between covariates and MCS12.

Covariates	Estimate	Std. Error	p value
Intercept	37.40	1.63	<0.001
Gender (Male)	-0.01	0.88	0.995
Education – Primary school	2.65	2.66	0.320
Education – High school	-0.73	1.01	0.471
Education – Middle school	-1.06	1.28	0.406
Pathology – Colitis	1.42	0.95	0.134
Disease activity – Moderate	-1.51	1.59	0.344
Disease activity – Remission	-0.61	1.27	0.632
Disease activity – Severe	-0.79	1.68	0.636
Smoking – Non smoker	-0.33	1.08	0.763
Smoking – Smoker	-0.08	1.28	0.950

HRQoL in patients with IBD using GAMs with DAG-informed confounding adjustment. This analytical framework captures not only whether an association exists, but also how the association varies across the range of self-care behaviours, offering a more refined interpretation than traditional linear approaches.

Self-Care Behaviours and Health-Related Quality of Life in IBD

In the present sample, physical HRQoL appeared relatively preserved, whereas mental HRQoL was substantially impaired, falling nearly 13 points below the general population norm. This pattern is consistent with previous evidence demonstrating that psychological burden, including anxiety, emotional distress, and uncertainty related to disease fluctuations, plays a central role in IBD, even among patients in clinical remission (Almarzouki et al., 2024; Mules et al., 2022; Thomann et al., 2023). In an Italian cohort of IBD patients in remission, 52% reported poor HRQoL and 45% had anxiety or depression (Larussa et al., 2020). Notably, 57.2% of participants in the present study were in clinical remission, yet MCS-12 scores remained markedly low, indicating that clinical remission does not necessarily correspond to full mental health recovery (Larussa et al., 2020; Mules et al., 2022). This finding may reflect the persistence of psychological and behavioural factors beyond inflammatory disease activity, including fear of relapse, illness uncertainty, chronic fatigue, and the continuous demands of symptom monitoring, which can maintain psychological distress despite mucosal remission (Mules et al., 2022; Thomann et al., 2023; Sheehan et al., 2024; Napolitano, Bozzetti, et al., 2026).

Regarding self-care behaviours, patients demonstrated higher SC-CII Monitoring scores (80.59 ± 17.63) compared to Maintenance (69.75 ± 11.33) and Management (68.79 ± 16.75). Using the established adequacy threshold of ≥70 (Vellone, Lorini, et al., 2020), mean Maintenance and Management scores fell below the cutoff, while Monitoring exceeded it. This pattern suggests that although patients may recognize symptoms and disease changes, translating this awareness into consistent health-promoting behaviors and timely management actions remains challenging (Napolitano, Cilluffo, Amatucci, et al., 2025). Similar findings have been reported in other chronic illness populations, where self-care monitoring tends to be better developed than maintenance and management behaviours (Cai et al., 2025; Kim et al., 2026).

This imbalance between symptom recognition (monitoring) and the implementation of effective self-care behaviours (maintenance and management) may reflect multiple interacting factors that have been identified in the broader literature, including psychological distress, the unpredictable course of IBD, and differences in health literacy, access to information, and social support (Demers et al., 2025; Napolitano, Bozzetti, et al., 2026). However, these factors were not directly assessed in the present study and should therefore be considered as potential explanations rather than mechanisms supported by our data. The characteristics of the study population further help explain these findings: participants were a relatively young cohort (mean age: 43.85 years) with substantial disease experience (mean duration: 11.64 years), suggesting familiarity with disease management. However, variability in educational background, ranging from primary school (3.3%) to bachelor's degree or higher (32.5%), may have limited patients' ability to convert disease knowledge into effective self-care maintenance and management behaviours, particularly those requiring decision-making and problem-solving skills (Magi et al., 2026).

Lifestyle factors, including smoking habits, also deserve attention, as smoking is known to negatively influence disease progression and outcomes, particularly in CD (Ananthakrishnan et al., 2022). Nurse-patient mutuality has been shown to positively influence all three self-care dimensions in IBD, with distinct relational dimensions linked to distinct self-care domains, highlighting the importance of therapeutic relationships in promoting self-care (Napolitano, Bassola, et al., 2026; Napolitano, Cilluffo, Marini, et al., 2025).

Self-Care and Physical Health-Related Quality of Life

DAG-adjusted GAMs did not reveal a significant association between SC-CII Maintenance or Monitoring and PCS-12. Model-based contrasts confirmed these null findings: moving from the 25th to the 75th percentile of Maintenance was associated with a negligible change in PCS-12, and a similarly null contrast was observed for Monitoring. These results suggest that routine

self-care activities and symptom awareness, while essential for disease control, may not directly translate into perceived improvements in physical functioning. In patients with IBD, physical HRQoL is influenced by multiple factors, including disease severity, comorbidities, and long-term physiological changes, which may not be substantially modified by self-care behaviours alone (Alkrinawi et al., 2026; Larussa et al., 2020). This finding is consistent with evidence from heart failure populations, where self-care maintenance showed a modest positive association with HRQoL, but monitoring and management did not demonstrate significant associations after accounting for symptom burden (Kim et al., 2026).

In contrast, SC-CII Management showed a statistically significant nonlinear association with PCS-12. The model-based contrast revealed Management was associated with a decrease in PCS-12. This finding may reflect the reactive nature of management behaviours, which are typically activated in response to symptom exacerbations or complications (Napolitano, Cilluffo, Amatucci, et al., 2025). Therefore, higher levels of self-care management may not indicate better health status, but rather a greater need to cope with disease-related challenges. Alternatively, disease activity may lie on the pathway between self-care behaviours and physical HRQoL, although the cross-sectional nature of the present analysis does not allow this potential mediating mechanism to be established. Patients who report more intensive management behaviours may actually be those experiencing worse physical conditions, a phenomenon consistent with the concept of "confounding by indication" in observational self-care research (Napolitano, Bozzetti, et al., 2026).

This interpretation aligns with evidence from COPD dyads, where increased self-care monitoring was correlated with reduced quality of life, suggesting that heightened symptom vigilance may reflect greater disease burden rather than better outcomes (Cai et al., 2025). Similarly, in heart failure populations, monitoring and management are activated by symptom exacerbations, and accounting for disease burden may dilute positive associations between these self-care dimensions and HRQoL (Kim et al., 2026).

Overall, the weak model fit highlights the multifactorial nature of physical well-being in IBD. While self-care remains a critical component of disease management, its impact on physical outcomes may be indirect and mediated by clinical and biological factors. These findings support a broader, more integrated approach to IBD care, in which self-care support is embedded in comprehensive clinical management. Evidence from IBD medical home models demonstrates that multidisciplinary care can significantly reduce unplanned healthcare utilisation and improve both disease activity and quality of life (Regueiro et al., 2018). Similarly, the IBD BIO-ASSIST randomised controlled trial showed that IBD nurse specialists improved quality of life in patients with impaired baseline well-being on biologic therapy, providing psychosocial support, care coordination, and patient education (Bokemeyer et al., 2024). Nurse-led follow-up models have also demonstrated non-inferior and, in the social domain, clinically superior HRQoL outcomes compared to conventional care (Alvestad et al., 2022).

Self-Care and Mental Health-Related Quality of Life

DAG-adjusted GAMs did not demonstrate a meaningful association between any SC-CII domain and MCS-12. The smooth terms for Maintenance, Monitoring, and Management were all non-significant.

Rather than contradicting previous evidence, these results support the hypothesis that the relationship may operate in the opposite direction. Psychological distress has been shown to significantly influence self-care behaviours, indicating that mental health may act as a key determinant of patients' ability to engage in effective self-care (Fu et al., 2020). Fear of disease progression, a prevalent concern among IBD patients, has been shown to negatively affect HRQoL both directly and indirectly through reduced health literacy and self-care capabilities (Moradkhani et al., 2013). This suggests that improving psychological support may be essential to enhance self-care engagement, rather than expecting self-care alone to improve mental well-being.

Mental HRQoL in IBD is widely recognised as a complex and multifactorial construct, shaped by elements such as emotional distress, uncertainty related to disease course, fear of relapse, illness perception, visceral sensitivity, and the broader

psychosocial impact of living with a chronic condition (Almarzouki et al., 2024; Thomann et al., 2023). Network analysis has identified depression as the most central factor in the biopsychosocial network influencing HRQoL in IBD, with visceral sensitivity and illness identity engulfment showing the strongest direct relationships with HRQoL (Thomann et al., 2023). Perceived stress, number of relapses, and perceived social support have been identified as the strongest predictors of HRQoL in multivariate models, with psychological symptoms partially mediating the relationship between disease activity and HRQoL (Fu et al., 2020; Moradkhani et al., 2013). In this context, self-care behaviours, although essential for disease management, may not be sufficient to address the psychological burden experienced by patients.

The lack of association may also reflect a dissociation between behavioural engagement and emotional adaptation. Patients may actively engage in self-care practices while still experiencing impaired mental well-being, highlighting that adherence and self-management do not necessarily translate into psychological resilience or improved emotional outcomes (Chin et al., 2021). Self-efficacy has been shown to mediate the relationship between patient activation and daily IBD burden, with a proportion mediated of 62%, suggesting that the pathway from self-care behaviours to psychological outcomes may be substantially indirect (Tiles-Sar et al., 2025). These findings underscore the importance of integrating psychological and supportive interventions into IBD care. Integrated psychological care models have demonstrated significant improvements in anxiety, depression, and mental HRQoL in IBD patients, with in-service psychological interventions showing six-fold greater engagement compared to external referrals (Lores et al., 2019).

Limitations

First, the cross-sectional design precludes any inference regarding causality or temporal relationships between self-care behaviours and HRQoL. Although the analyses identified associations, it remains unclear whether self-care influences HRQoL, whether HRQoL affects self-care engagement, or whether both are influenced by unmeasured common causes. Although the sample size was determined a priori for the parent IBD-SELF study, it was not specifically calculated for the GAM-based secondary analyses reported here. Therefore, the possibility of limited statistical power to detect small or complex nonlinear associations cannot be completely excluded. Second, self-care and HRQoL were assessed through self-reported questionnaires. Consequently, the findings may be affected by recall bias, response bias, and social desirability bias, potentially leading to overestimation of self-care behaviours. Third, several psychosocial variables known to influence both self-care and HRQoL in IBD, such as anxiety, depression, resilience, coping strategies, self-efficacy, and social support, were not included in the analyses. Although the DAG-informed approach allowed adjustment for major sociodemographic and clinical confounders, residual confounding cannot be excluded. Moreover, although disease activity was treated as a potential confounder in the prespecified DAG, an alternative causal structure in which self-care behaviours influence disease activity, which subsequently affects HRQoL, is also theoretically plausible. Such a pathway would position disease activity as a potential mediator rather than solely as a confounder. Given the cross-sectional design, temporal ordering cannot be established and this alternative pathway could not be formally evaluated. Future longitudinal studies should therefore examine whether disease activity mediates the relationship between self-care and HRQoL. Notably, fear of disease progression, which has been shown to independently affect both self-care and HRQoL through mediating pathways involving health literacy, was not measured. Finally, participants were recruited from specialised outpatient IBD centers across Italy. Therefore, the findings may not be fully generalisable to individuals receiving care in different healthcare settings, healthcare systems, or cultural contexts.

Despite these limitations, the study benefits from a large multicentre sample (n = 453), the use of a theory-based and IBD-validated measure of self-care (SC-CII), and the application of innovative statistical approaches, including DAG-informed confounding adjustment and generalized additive modelling, providing a robust framework for investigating complex relationships between self-care and patient-reported outcomes in IBD.

Implications for Practice and Research

The findings of this study carry several implications for clinical practice and future research. First, the limited direct association between self-care behaviours and HRQoL suggests that nursing and clinical interventions should move beyond a sole focus on self-management education and incorporate strategies aimed at addressing emotional well-being, nutritional, resilience, and patient empowerment (Ribaudi et al., 2025; Said et al., 2026). IBD nurse specialists are well positioned to deliver such integrated support, as evidence demonstrates their role in improving quality of life, care coordination, and psychosocial outcomes (Bokemeyer et al., 2024; Napolitano et al., 2020, 2022; Napolitano, Scaldaferri, et al., 2025).

Future longitudinal studies are needed to clarify the causal pathways linking self-care, psychosocial determinants, and HRQoL outcomes. Mediation analyses incorporating self-efficacy, resilience, health literacy, and psychological distress as potential mediators would help elucidate the mechanisms through which self-care behaviours influence or are influenced by patient-reported outcomes. Mixed-methods designs integrating qualitative exploration of patients' lived experiences with quantitative modelling may further enrich understanding of these complex relationships.

Conclusions

This multicentre study explored the relationship between self-care behaviours and HRQoL among 453 individuals living with IBD using GAMs with DAG-informed adjustment. Despite substantially impaired mental HRQoL and suboptimal self-care Maintenance and Management scores, self-care dimensions were not meaningfully associated with MCS-12 and showed only a weak and nonlinear association with PCS-12. These results suggest that self-care behaviours alone may be insufficient to explain variations in patients' perceived well-being. HRQoL in IBD appears to be influenced by a complex interplay of clinical, psychological, and behavioural factors that extend beyond routine self-care activities. Consequently, nursing care should incorporate strategies to address emotional well-being, resilience, and patient empowerment alongside self-management support.

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Original Research

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Developing, Piloting and Evaluating a Therapeutic Programme for Neonates Using the Plan-Do-Study-Act Framework

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Abstract

Introduction. Complicated births are often associated with functional disorders in neonates. Some literature suggests alternative therapies (e.g. Craniosacral Therapy (CST) and parental education) as an appropriate substitute for stronger interventions in such cases. This pilot study aimed to develop, implement and evaluate a therapeutic programme for neonates with functional disorders based on CST and parental education in a university hospital setting.
Methods. The Plan-Do-Study-Act framework was used. The programme, named 'Wellcome', was developed using an interprofessional approach. Pain, agitation symptoms and breastfeeding problems were the functional disorders targeted. A pilot phase was implemented to investigate: i) programme usage, ii) experience of it and attitudes towards it, iii) its operationalisation, and iv) its clinical effects. Quantitative and qualitative data were collected. A stakeholder dialogue completed the evaluation phase, and a roadmap was developed for future implementation steps.
Results. The pilot phase included 25 neonates, selected mostly for breastfeeding problems (72%). The attitudes towards Wellcome were generally positive. However, several aspects of its operationalisation (e.g. inclusion criteria) should be revised based on a combination of literature research, interprofessional exchange, and possibly primary research.

The pilot study showed that the clinical effects were generally positive, although vaguely described.
Discussion. The goal described in the roadmap was to proceed with piloting and collect further data. In parallel, conflicting points regarding inclusion criteria, human resources, and scientific evidence must be addressed in a structured manner. The structure envisages an iterative process that allows rapid progression without losing the momentum gained during this first pilot phase.

Keywords: Newborn, Complicated Birth, Functional Disorders, Complementary Therapies, Quality Improvement, Pilot Study

Introduction

Despite a lack of consensus regarding a single, unifying definition, 'complicated births' are often defined as those requiring the use of instruments (forceps or vacuum) or unplanned caesarean sections (Andersson et al., 2016; Jardine et al., 2020). It has been shown that complicated births place high physiological and biomechanical stress on the neonates, with, for example, up to 200 N of additional force applied to their heads when using vacuum or forceps compared to non-instrumented delivery (Ashton-Miller & DeLancey, 2009). For this reason, complicated births are often associated with functional disorders, such as pain or distress symptoms with agitated behaviour (Mears et al., 2004; Schuller et al., 2012; Taylor et al., 2000), breastfeeding problems (Chien & Tai, 2007), or reduced cervical range of motion (often presenting as 'Positional Preference') (Fludder & Keil, 2018). As the detection of such functional disorders is not necessarily included in the medical examination of neonates during hospitalisation, they are rarely treated at this stage. When left untreated, these disorders may persist and have repercussions on the neonates' development (Boere-Boonekamp & Van Der Linden-Kuiper, 2001; Noto et al., 2021). Parents may also suffer anxiety or a sense of failure due to increased crying periods of their baby (Garratt et al., 2019).

There is some evidence that manual approaches, such as craniosacral therapy (CST), can help improve these functional disorders, particularly when used as an adjunct therapy (Deitermann & Jung, 2015; Hathaway et al., 2015; Herzhaft-Le Roy et al., 2017; Sacher et al., 2022; Shayani & Marães, 2023). More generally, the use of such complementary and alternative medical treatment options has been suggested as a means to avoid premature use of stronger interventions, such as pharmacological treatment, which bear higher risks of side-effects and can be more invasive (e.g. Hathaway et al., 2015; Shayani & Marães, 2023). However, these studies often present mixed results or methodological limitations, such as small sample sizes, highlighting the need for more research in this field. Thus, the aim of this pilot study was to develop, implement and evaluate a new therapeutic programme based on CST that focuses on neonates from complicated births and with birth-related functional disorders. The novelty of the programme lied in the combination of CST and parental education. Moreover, the novelty of this work lied in the possibility to introduce alternative treatment approaches into a university hospital setting to further support the application of the biopsychosocial healthcare model, or even the biopsychosocial-spiritual model, as advocated by some authors (Saad et al., 2017). The results of this study served as a basis for informed decision-making regarding further implementation steps and the creation of a project roadmap for a larger implementation study.

This manuscript follows the SQUIRE 2.0 framework to present the pilot study (Ogrinc et al., 2016).

Methods

Context

In Switzerland, university hospitals are the ideal environment for assessing such a therapeutic programme, given they are primary healthcare providers and therefore see high numbers of complicated births, and given their proximity

to universities, which provide the necessary scientific expertise. The University Hospital of Bern has strong connections to both Bern University of Applied Sciences and University of Bern, making it an ideal clinical environment to conduct this study. An interesting aspect of this study was the readiness of the institution to investigate non-traditional treatment approaches.

Genesis and specific objectives of the project

The project of implementing a new therapeutic programme grew organically. The idea was developed by physiotherapists at the Department of Obstetrics and Gynaecology, who began to discuss it informally with other healthcare professionals to gauge interest. The idea was well received and they contacted the Academic-Practice-Partnership research unit unit at Bern University of Applied Sciences, which specialises in conducting collaborative scientific projects with University Hospital of Bern.

The specific objectives of the project were formalised by the research team as:

1. Developing a therapeutic programme delivered by physiotherapists to neonates from complicated births and with functional disorders, as an adjunct therapy, to improve their symptoms.
2. Implementing the programme as a pilot phase.
3. Evaluating the pilot phase to obtain a fundamental dataset.
4. Discussing and deciding on further steps of implementation based on the dataset and creating a project roadmap.

To achieve these objectives, the 'Plan-Do-Study-Act' (PDSA) framework (Berwick, 1998) was used (Figure 1). Given the different healthcare professions involved in this context – including midwifery, nursing, lactation consultation, physiotherapy, and medicine (neonatology, obstetrics, gynaecology) – an interprofessional, participative approach was used (e.g. Mairhofer, 2015). In this process, the initiating group of physiotherapists (n=3) formed the development team. The other healthcare professionals formed an active advisory board to guide the development, and their consent had ultimately to be gained to participate in the programme's workflow once implemented. The entire process was orchestrated by the research team of the Bern University of Applied Sciences and is detailed in the section "Development process of the therapeutic programme".

The PDSA framework describes an iterative process frequently used in quality improvement projects. Its circular nature means it does not have the achievement of a state of 'optimal quality' as its goal, but aims to continuously improve quality. The PDSA framework was

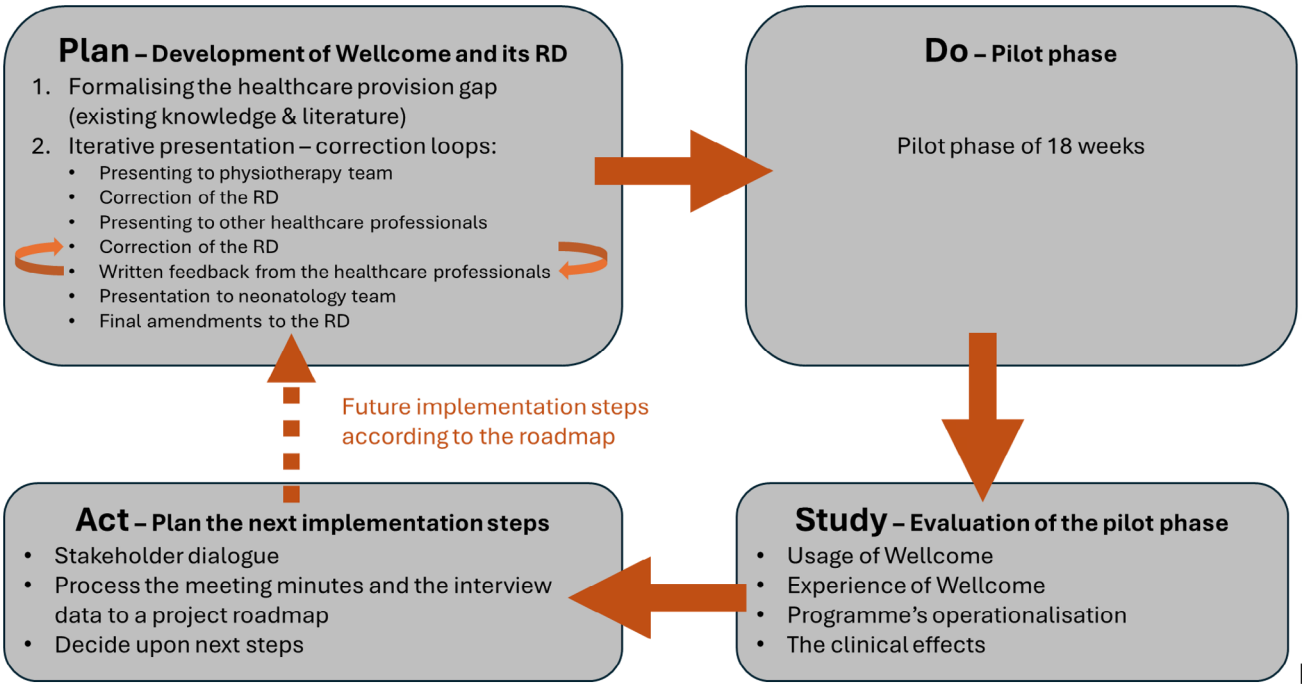


Figure 1. Plan-Do-Study-Act (PDSA) cycle used in this pilot study.

therefore selected as an ideal tool to achieve the aims of this study. The 'Plan' phase represents the planning of the intervention to be implemented, the 'Do' phase represents the implementation phase, the 'Study' phase represents the evaluation of the implementation and the lessons learnt, and the 'Act' phase represents the planning of the next steps, based on informed decision-making (Langley et al., 2009). Concrete operationalisation of these phases is described in the following sections.

Intervention: The 'Plan' phase

Development process of the therapeutic programme

Stemming from the organic genesis of the project, named Wellcome, the 'Plan' phase started with a certain supportive network. Then the network was broadened to ensure sufficient support and to obtain formal authorisation to launch a pilot phase. For this purpose, an interprofessional, participative approach was followed in an iterative process, which fed into the task of refining the Wellcome programme and writing its reference document (RD). The first step was to formalise the gap in healthcare provision. The physiotherapists were asked by the research team to list the types of functional disorder they perceived as necessary to target and to provide a working definition of 'complicated birth'. The results were compared to the available scientific literature to identify overlapping perspectives and to generate a first literature-based list of inclusion criteria for Wellcome. The same procedure was followed for the therapeutic intervention that was intended to be delivered by the physiotherapists themselves. Based on these data, the first version of the RD was drafted.

In the next step, the RD was repeatedly presented to a panel of healthcare professionals not engaged in the project and updated based on critical feedback obtained during these presentations. The first presentation was performed with the entire physiotherapy team and the supervisor to reach acceptance, if not consensus, within the team and the authorisation to proceed with the project. The second presentation was performed with nurses (n=2), midwives (n=2) and lactation consultants (n=2). This was an important step because these healthcare professionals would be involved in Wellcome. To prepare this presentation, a stakeholder analysis within these professions was performed to determine key invitees. Final decision on recruitment was based on their clinical experience and strategic roles as supervisor in their respective teams. Besides obtaining general feedback, the main focus was to gather their opinions on the proposed inclusion criteria (including the definition of a 'complicated birth' and the list of targeted functional disorders) and on the choice of standardised clinical assessment tools to evaluate the functional disorders. After updating the RD based on their feedback, intermediate steps were taken in which the RD was iteratively sent to them for review and revised until consensus was reached. The third presentation was performed with the neonatology team during one of their weekly meetings to reach as many neonatologists as possible. The neonatologists' feedback was used to finalise the RD. The authorisation of both neonatology's and gynaecology's head physicians was obtained to launch a pilot phase according to the updated RD.

The implemented version of the Wellcome programme

Wellcome targeted neonates from complicated births, defined as those requiring secondary caesarean section due to malposition of the foetal head or obstructed labour, or forceps or vacuum extraction deliveries. Among those births, neonates with agitation and/or pain symptoms as well as neonates with breastfeeding problems that could not be resolved by lactation consultants were included. Only neonates from the well-baby nursery born at term were considered for the programme. They were required to breathe spontaneously.

For the agitation and pain symptoms, the evaluation of the inclusion criteria was performed by nurses and midwives using the Bernese Pain Scale for Neonates (BPSN, score range: 0-17). Within a period of 12 hours after birth, neonates were assessed every four hours using the BPSN with a cut-off value of ≥4. According to Schenk et al. (2020), a score of ≥4 indicates pain in neonates. Breastfeeding problems were evaluated by the lactation consultants, but no consensus could be reached on a standardised assessment tool. The evaluation was based on clinical experience, mainly assessing latch quality, pain symptoms in mothers (i.e. nipple soreness), and nipple shape. Neonates that met the inclusion criteria were discussed during the neonatologist's rounds. Referral was performed by the neonatologist. The

workflows are shown in Figure 2.

The treatment included an assessment and individualised therapy. The assessment comprised an anamnesis from the parents and a physical examination of the neonates, focussing on muscle tone anomalies, asymmetries and articular ranges of motions. Therapy included CST and/or parental education, including exercises and handling instructions to foster symmetry and reduce agitation symptoms. Retest of the symptoms by the other healthcare professionals was planned 24 and 48 hours after birth.

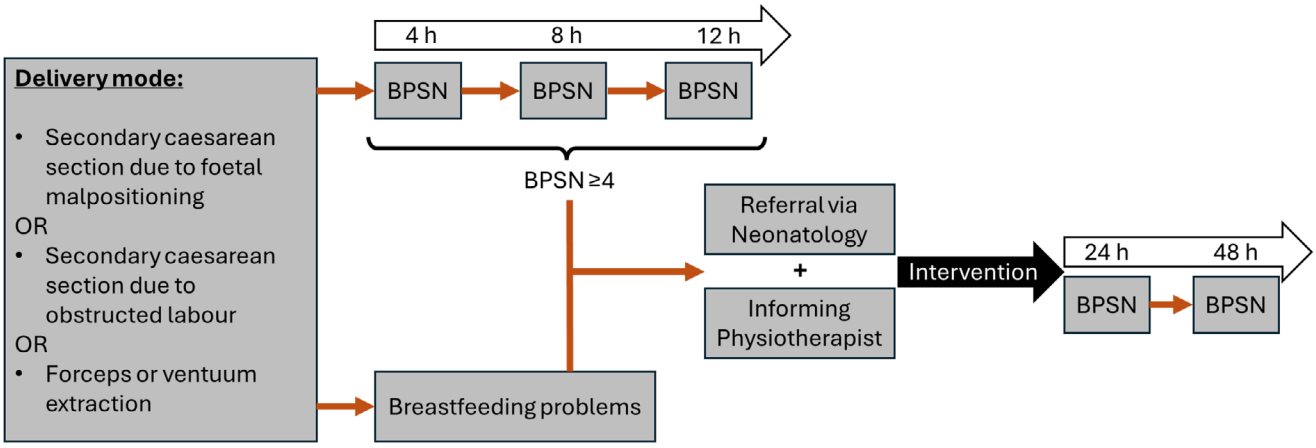


Figure 2. Illustration of the workflow defined in the RD. BPSN: Bernese Pain Scale for Neonates.

Implementation: The 'Do' phase

The pilot phase was planned for a period of four months. All nurses, midwives, lactation consultants and physicians from the postpartum ward were informed in advance about the pilot phase via email. Educational sessions, consisting of a series of 45-minute workshops, were organised to instruct them regarding their role in identifying neonates who met the inclusion criteria and how to initiate referral to the Wellcome programme. The reason why a whole series was required is that with the shifts, not all employees were present at the same time. Hence, the workshop needed to be repeated several times. During the pilot phase, no changes were made to the RD.

Study of the intervention, measures, and analysis: The 'Study' phase

General approach

Four aspects of the pilot phase were investigated: i) quantifying the usage of Wellcome, ii) exploring parents' and employees' experiences of and attitudes towards Wellcome, iii) evaluating the current operationalisation of Wellcome (i.e. how it was implemented, how the implementation was experienced, and how the workflows defined in the RD were perceived and followed), and iv) assessing the therapeutic effect, given the currently controversial state of evidence (Ceballos-Laita et al., 2024; Jäkel & von Hauenschild, 2012). In addition, although no adverse events are known from the literature on CST (Ceballos-Laita et al., 2024), the occurrence of adverse events was monitored to ensure safety of healthcare provision. Both therapeutic effects and adverse events are jointly termed 'clinical effects' hereafter.

Data collection, processing and analysis

Both qualitative and quantitative data were collected anonymously. Qualitative data were collected through semi-structured interviews performed during the last two weeks of the pilot phase with parents of treated neonates and with involved healthcare professionals (i.e. 'employees'). The interview guideline was drafted by the first author and sent to the other research team members for internal validation. The interviews with parents focussed on their experience of and attitude towards Wellcome. The interviews with employees had three foci: i) experience of and attitude towards Wellcome, ii) the level of satisfaction with its operationalisation, and iii) its perceived clinical

effects. All participants were also asked what they would suggest improving. Employee participants were recruited via advertisement posted on internal communication channels or addressed personally. All parents within the recruitment period were visited and asked whether they were interested in participating in the study. Given the early stage and the exploratory nature of the project, no specific sample size nor data saturation was targeted. The interviews were performed in person or over the phone. In-person interviews were audio-recorded using a voice recorder (Zoom H1essential, Tokyo, Japan) and phone-based interviews via MS Teams. All interviews were processed using the Rapid Identification of Themes from Audio Recordings method (Neal et al., 2015). Coding was performed by two members of the research team (LS and AC) independently. Individual results were compared and discussed to reach consensus. Themes were generated deductively and inductively for each interview focus and summarised in a MS Excel (v. 2308) document. The number of statements per theme with their valence (i.e. positive, neutral or negative statement) were summed (Neal et al., 2015). In addition, the evaluators' respective interpretations of the statements as well as their perceived importance and the statements' contexts was discussed to allow appropriate appreciation.

Quantitative data were retrieved from the clinical information system in an anonymised format after the pilot phase. These data consisted of the number of neonates included in the Wellcome programme, their respective clinical indications, the number of days between birth and first treatment, the number of treatments delivered per neonate, the number of times the workflows deviated from those defined in the RD, the changes in scores from the standardised clinical assessment tools used to evaluate the functional disorders, and the number of adverse events. The data were extracted into MS Excel, where they were synthesised using descriptive statistics (frequencies: absolute and percentage; distributions: median, minimum and maximum).

The four aspects of the pilot phase were evaluated as follows.

1. Usage of Wellcome was evaluated based on the number of neonates included with their respective clinical indications, as well as the number of treatments delivered per neonate.
2. The experiences of and attitudes towards Wellcome were explored using the interview data.
3. The programme's operationalisation was evaluated quantitatively using the time to treatment and the frequencies with which the identification of eligible neonates, the objectivation of their functional disorders and their referral to the programme complied with the RD, as well as qualitatively using the interview data.
4. The clinical effects were assessed using the changes in scores from the standardised clinical assessment tools as well as from the employees' perceptions obtained from the interviews. In addition, the number of adverse events was counted.

Planning of the next steps: The 'Act' phase

To discuss further implementation steps, a stakeholder dialogue was performed, to which the previously recruited stakeholders from nursing, midwifery, lactation counselling, neonatology, as well as members of the research team (KS and LS) were invited. The stakeholders' positions regarding the implemented version of Wellcome as well as future implementation steps were discussed in light of the results from the 'Study' phase. Discussion minutes were taken. A fair copy was written and sent to all stakeholders for validation. They were allowed to amend the copy if required.

The stakeholder dialogue, together with the interview data, formed the basis of a project roadmap. The text passages from the meeting minutes were first grouped thematically into categories and subcategories. A summary outlining the main consensual and conflicting points was composed for each subcategory. The conflicting points and unresolved questions were listed together with a corresponding list of tasks to tackle them. Finally, links between these points requiring action to be resolved were identified, allowing a brief network analysis using MS Excel. In this analysis, a link represented the case where a task structurally depended on another. Subcategories were ranked according to their number of links to other subcategories, i.e. degree centrality (Rodrigues, 2019), to prioritise tasks in the roadmap.

Ethical considerations

No ethical approval was required for this project since it did not fall under the Swiss Federal Human Research Act (Req-2024-00513). Nonetheless, the Declaration of Helsinki was respected. Informed consent to collect data was obtained from all included neonates' parents once they had started the programme.

Results

Results from the Study phase

All required quantitative data could be retrieved from the clinical information system. For the interviews, there was a total of 13 participants. Five interviews were conducted with parents. From the employees (7 female, 1 male), two were neonatologists, two physiotherapists, two midwives, one nurse and one lactation consultant. Overall, they had a median working experience of 12.2 years (range: 1.5–35).

Usage of Wellcome

The pilot phase lasted 18 weeks (~4.5 months). In this period, 25 neonates were included in Wellcome. Most cases were included due to breastfeeding problems (n=18, 72%), followed by agitation and/or pain symptoms (n=2, 8%) and a combination of both (n=3, 12%). Other symptoms, such as foot deformities and parental worries, were included in two cases (8%). A median of one treatment was delivered per case. One treatment was delivered in 20 cases, and a maximum of two treatments was delivered in five cases.

Experience of and attitudes towards Wellcome

Parent interview data were categorised into three themes: 'Physical symptoms', 'Psychological symptoms, stress, and mental wellbeing', and 'Embeddedness in hospital stay' (Table 1). No negative statements were provided for any theme. In total, 19 positive and five neutral statements were provided for this interview focus. The favourable attitude towards Wellcome was due to 42% (n=8 statements) to experiencing improvements in physical symptoms, mainly feeding- and digestive or urinary system-related symptoms, and stiffness symptoms that hindered physiological head movements. In addition, 32% (n=6 statements) of the answers reflected a positive effect on parental psychological state and stress levels, as well as improved calmness of neonates. Interestingly, some interviewees described their experience as positive but were unable to define the reasons. Finally, 26% of the positive statements concerned the embeddedness of the programme in the parents' hospital stay, including the fact that Wellcome is a low-threshold service, and that the symptom improvements led to a reduced use of the nurse call bell. Neutral statements consisted of one case that found it difficult to evaluate the benefit and other encouraging words supporting the permanent implementation of the programme.

Employee interviews were categorised into two themes: 'Meaningfulness', with 12 positive and one negative statement; and 'Values', with 10 positive and one neutral statement. It was mentioned by all interviewees that Wellcome was meaningful, even though this view was sometimes based on knowledge of what the programme intended to achieve rather than on personal experience of its benefits. Wellcome was described as a meaningful adjunct to cover an important gap in healthcare provision, particularly because it facilitated identification and treatment of functional disorders early in a neonate's life. Moreover, it was seen as a great support to alleviate parental stress. The notion of 'providing an optimal start in life' was also perceived as an important value the programme represents. Also, provided it is not harmful, the programme was valued as one more service that increases the chances to promote neonates' health, hence it is worth adding. This was particularly influenced by its perception as a low-threshold service. However, one interviewee critically questioned its meaningfulness in relation to best use of human resources when the programme is based on limited scientific evidence and this is a time of skills shortage. One neutral statement noted the need to obtain parental consent before beginning treatment, irrespective of any perceived value of the programme.

Evaluation of the operationalisation

The median time between birth and first

treatment was two days. In three cases, the treatment was initiated the same day, in nine cases after one day, in eight cases after two days, in four cases after three days, and in one case after four days. Out of the five neonates included for agitation and/or pain symptoms (n= 2 plus n=3 in combination with breastfeeding problems), only one was evaluated using the BPSN. The other case did not include objectivation of the symptoms and the reasons could not be elucidated. Given that no consensus could be reached on an assessment tool for breastfeeding problems, no compliance analysis could be performed for these cases. Referral was performed according to the workflows described in the RD 32% of the time (n=8). Most cases (n=17, 68%) were not referred according to the set workflows, with most deviations (n=15, 60%) being the inclusion of neonates that did not meet the birth criteria. The remaining 8% comprised a neonate that experienced a forceps delivery but did not meet the set scope of functional disorders and one that met no criteria at all.

The interview data contained 10 positive, seven neutral and 27 negative statements on how the implemented version of Wellcome was experienced (Table 1). The positive statements mostly comprised feedback on the workflows themselves (50%), which were most frequently considered to be straightforward, and on the interprofessional collaboration (40%). The same themes contained the most negative statements. Statements concerning the interprofessional collaboration (33%) most frequently contained feedback on heterogeneous levels of acceptance regarding Wellcome among colleagues and insufficient introduction to the programme. The negative statements on 'Workflow' (30%) mostly referred to the additional effort imposed by Wellcome (e.g. performing the BPSN repeatedly or having to remember to identify eligible neonates and refer them to the programme in an already hectic clinical routine). Another substantial theme on the negative feedback side consisted of the inclusion criteria (19%), which covered contradictory statements. On the one hand, a group of interviewees felt that the inclusion criteria were too restrictive. Inclusion of neonates based strictly on pain/agitation symptoms and breastfeeding problems was thought to result in excluding many cases with other symptoms that could have benefited from Wellcome. Similar feedback was provided regarding the BPSN cut-off value of ≥4, which was thought to be too high. It was also proposed that inclusion should rely less on criteria and more on evaluation based on clinical experience. On the other hand, the lack of clear inclusion criteria for breastfeeding problems was also criticised and the only positive feedback in that theme was that the BPSN provided clarity due to its objective nature. A final theme labelled 'Others' mostly covered statements deploring a difficult starting phase due to insufficient information and presence of the programme

Table 1. Interview foci and themes identified using the Rapid Identification of Themes from Audio Recordings method from parent and employee interviews. The number of positive, neutral and negative statements are presented.

	Interview focus	Theme	Statements		
			Positive	Neutral	Negative
PARENTS	**Experience & Attitudes**		**N=19**	**N=5**	**N=0**
		Physical symptoms	n=8	n=2	n=0
		Psychological symptoms	n=6	n=0	n=0
		Embeddedness	n=5	n=3	n=0
EMPLOYEES	**Experience & Attitudes**		**N=22**	**N=1**	**N=1**
		Meaningfulness	n=12	n=0	n=1
		Values	n=10	n=1	n=0
	Operationalisation		**N=10**	**N=7**	**N=27**
		Workflows	n=5	n=0	n=8
		Interprofessional collaboration	n=4	n=4	n=9
		Inclusion criteria	n=1	n=1	n=5
		Others	n=0	n=2	n=5
	Clinical effect		**N=12**	**N=3**	**N=2**
		Agitation	n=4	n=0	n=1
		Breastfeeding	n=3	n=0	n=1
		Mother-child dyad	n=2	n=0	n=0
		Others	n=3	n=3	n=0

initiators, as well as the implementation being timed in parallel with the launch of a new clinical information system. The statements regarding the later stage of the pilot phase confirmed that these aspects had improved. The seven neutral statements concerned the same aspects as the positive and negative statements under the 'Interprofessional Collaboration' (57%), 'Inclusion Criteria' (14%), and 'Others' (29%) themes, but were simple descriptions of their experiences, without judgement.

Clinical effect

The BPSN was performed once to include a neonate and evolved from a score ranging from 4 to 5 up to 20 hours postpartum, to a score of 3 after therapy. No quantitative analysis could be performed for the therapeutic effect on breastfeeding problems since no standard assessment tool was used. No adverse event was reported.

The interview data showed 12 positive, three neutral, and two negative statements in four themes (Table 1). Most positive feedback was provided on improvements in agitation symptoms (33%). One interviewee had observed these improvements, two heard of them via parental feedback, and one reported the improvements based on both. Second most frequent positive effect was reported on breastfeeding problems (25%), which was directly observed by two interviewees out of three. The positive effect on the mother-child dyad was also mentioned (17%), particularly as a secondary effect from the decreased parental stress. The remaining statements (25%) were categorised under the theme 'Others' and grouped statements on the positive experience of parents who were involved in the therapy via the educational part of the intervention, as well as the theoretical benefit of the programme. Two neutral statements mentioned that the general effect (i.e. concerning all themes of this interview focus) was unclear. This was moderated by a third statement advancing the view that if there were no benefit, at least there was certainly no harmful effect. Two statements were more critical. One warned that some functional disorders could improve without treatment, as was observed by the interviewee directly in an eligible neonate that ended up receiving no therapy. The other reported, from direct observation, no effect in two out of five breastfeeding problems.

Results from the Act phase

The stakeholder dialogue gathered six participants, such that all invited professions were represented by at least one person. After the dialogue, the meeting minutes was amended by two persons, while one person reported having no comments and three did not respond. From the corrected meeting minutes, eight subcategories were identified, which were grouped into four categories (shown in Figure 3). The subcategories are ranked in Table 2 according to their priorities, based on degree centrality, and presented grossly with their most important conflicting points and unresolved questions that must be addressed, along with suggested approaches. Figure 3 presents a graphical representation of the resulting roadmap. It was designed as an iterative process with two 'routes'. First, the 'knowledge route', whereby a common knowledge base shall be obtained, primarily regarding inclusion criteria (including the definition of a complicated birth). This should be performed through scientific literature research and interprofessional work shadowing to synthesise best current evidence and to level the practices, respectively. Second, the 'exchange route' foresees interprofessional discussions to develop improved inclusion routines and to decide upon the amount of evidence required to justify definitive implementation from a resource and ethical perspective. These discussions shall be informed by the work done in the knowledge route. After each cycle, the RD will be updated and a new pilot phase chapter will be launched, generating further data and gaining additional experience. In parallel, other tasks (e.g. preparing information flyers, or discussing general prescription possibilities) could be performed relatively independently of the order of the two routes. It is important to note that the roadmap explicitly recommends planning many iterations, each with reasonably small goals that can realistically be achieved in a relatively short period of time. This has the advantage of a short discontinuation period of Wellcome, therefore the benefits of the first pilot phase's momentum can be utilised. The full roadmap can be found in the supplementary material.

Table 2. Subcategories identified from the meeting minutes of the stakeholder dialogue ranked according to their degree centrality in descending order.

Inclusion Criteria (Degree Centrality: 9)

It is unclear whether more or less objective criteria should be used. Objective criteria would foster evidence-based medicine. However, psychometric properties of existing assessment tools, most reliable time point to use them and the time/effort required to use them are unclear. In contrast, even in medicine many interventions are not evidence-based, such that a less criterion-based approach (i.e. need-oriented) could be considered. The question to tackle is:

What are the optimal inclusion criteria (from an evidence-based practice, ethical and resources perspective)?
Suggested approaches:

- Systematic literature review to map existing assessment tools and list respective: psychometric properties (reliability, diagnostic validity, predictive values), time/effort required to perform, and most reliable time points to use.
- Interprofessional work shadowing to compare knowledge and perspectives.

Resources (Degree Centrality: 7)

It is unclear whether the required human resources can be justified for a programme that has weak evidence. From this perspective, Wellcome could be interpreted as a wellbeing programme (i.e. need-oriented). The majority of resources would be at the expense of the physiotherapy team. Other professions did not report substantial additional time costs involved with Wellcome, except for performing the BPSN, which is time-consuming. The question to tackle is:

What are the criteria to justify the resources required for Wellcome (in terms of scientific evidence, hospital policy, and operationalisation efficiency)?
Suggested approach:

- Discuss with hospital managers/supervisors how many resources can be mobilised for a given level of scientific evidence, based on current hospital policy and on the knowledge from the previous literature review on operationalisation efficiency (i.e. time required for a given assessment tool with a certain diagnostic sensitivity and specificity).

Evidence (Degree Centrality: 7)

Insufficient therapeutic evidence was obtained from the pilot phase to draw any conclusion. But given the preliminary results appear to be relatively positive, the programme should be continued to collect further data. Then, plans for a more robust scientific investigation could be discussed. However, it is unclear how much evidence is required. The question to tackle is:

What is the 'right amount' of evidence and how can it be generated?
Suggested approach:

- Improve the programme based on the previous systematic literature review (Inclusion Criteria) and proceed with the programme to collect further data for another approximately seven months (i.e. dataset from a total duration of approximately 12 months).
- Based on the collected data, further scientific steps should be discussed with managers/supervisors regarding the required evidence and with research partners regarding research options.

Time Points (Degree Centrality: 3)

It is unclear whether assessing the targeted functional disorders as shortly after birth as was performed was beneficial. The same holds true for the intervention. It is conceivable that assessment tools are insufficiently sensitive so early in life and that neonates with seeming indications could possibly regulate themselves without intervention. However, hospital stay is very short, therefore a longer wait is not feasible. The question to tackle is:

What are the optimal time points to assess and treat the neonates?

Suggested approach: These aspects are covered in Inclusion Criteria and Evidence.

Others (Degree Centralities: 0–3)

Other aspects of less importance due to lower degree centrality values, less significance to the programme and/or requiring less preparatory work, included:

- **Effect:** investigating the natural history of the targeted functional disorders to obtain a better understanding of what to expect from the intervention.
- **Dissemination & Opposition:** distribute flyers, present current results to the teams, and directly address colleagues with negative attitudes to promote Wellcome and reduce opposition to it.
- **Referral:** investigate ways to improve referral efficiency (e.g. possibility for general prescription).

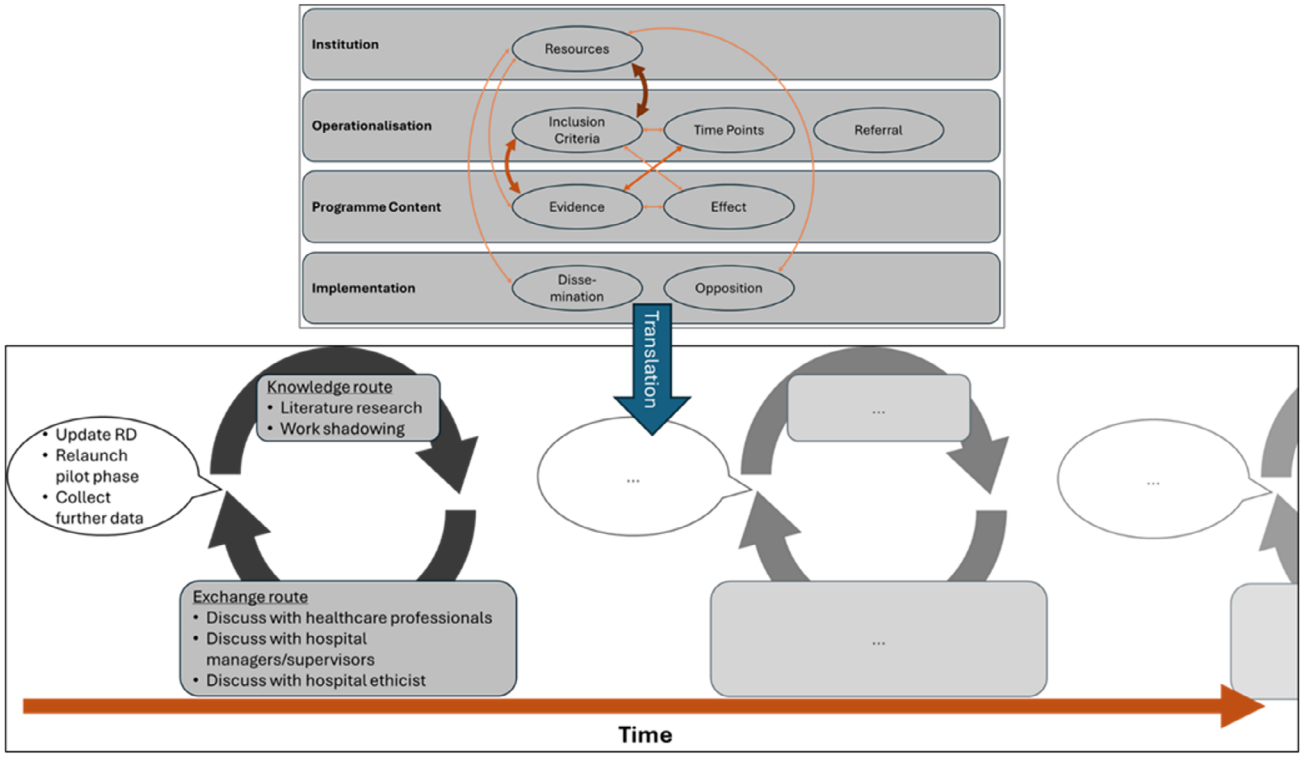


Figure 3. Top: illustration of the (sub-)categories identified from the meeting minutes of the stakeholder dialogue with their interconnectedness (orange arrows). The stronger the connections (i.e. higher degree centralities), the bolder and darker the arrows. Bottom: these topics were translated into the roadmap, which is represented as repeated cycles over time.

Discussion

In this pilot study, a therapeutic programme based on CST and parental education was developed in an interprofessional team to improve healthcare provision for neonates with functional disorders. The programme was implemented in a 18-week pilot phase, during which data were collected to evaluate programme usage, experience of and attitudes towards it, its operationalisation, and its clinical effects. The results of the evaluation showed that the programme found traction, given it included a total of 25 neonates, equating to a weekly average of 1–2 new cases, and given that most attitude- and experience-related feedback from parent and employee interviews was positive. Most positive parental views concerned perceived physical or mental benefits from the intervention, although precise descriptions were often lacking. Employees' positive attitudes mainly related to the perceived meaningfulness of Wellcome and the values it represents. Based on these results, it was suggested in the stakeholder dialogue to proceed with further piloting to collect additional data and gather more experience.

Several negative points were also raised during the pilot phase. Negative feedback from the interviews focussed mainly on how the programme was shaped and/or implemented (i.e. additional effort, suboptimal inclusion criteria, lack of acceptance by some colleagues). These results were reflected in the quantitative analysis, which showed lack of adherence to the workflow and criteria described in the RD in 68% of the cases. These topics were corroborated by the stakeholder dialogue. Taken altogether, these results allowed a prioritisation of the observed concerns. A major and multifaceted issue arose in the inclusion criteria. For example, some proposed less strict criterion-based selection, while others suggested adding further criteria, e.g. for breastfeeding problems, to improve clarity in decision-making. The issue also has implications for other aspects of the programme that were criticised, such as the utilisation of human resources. Choosing shorter pain/agitation assessment tools could, for instance, alleviate the additional effort imposed by Wellcome's workflow. More importantly, the issue of suboptimal inclusion criteria raises the question to what extent additional human resources can be mobilised if the indications remain vague. In any case, refining inclusion criteria appears to be highly important, since not respecting them represented 60% of all cases where the procedure deviated from the defined workflow.

More generally, it is unclear how much scientific evidence is required to justify the definitive implementation of Wellcome. Not only is this a question of resource utilisation, but it is also an ethical question (e.g. Vineis, 2004), asking whether neonates should be treated with CST and whether workforce should be used for this purpose if the evidence for clear indications and for efficacy is weak.

In any case, this situation also leads back to the need to collect further data and, on a more general level, to acquire a stronger knowledge base, also from the literature. For example, while two systematic reviews indicate weak efficacy results for CST (Ceballos-Laita et al., 2024; Jäkel & von Hauenschild, 2012), other studies that were not included in these reviews appear to show positive effects on breastfeeding (Herzhaft-Le Roy et al., 2017) and on length of hospital and/or newborn intensive care unit stay for preterm babies, with a reduction ranging from 3.9 to 5.9 days (Cerritelli et al., 2013, 2015; Pizzolorusso et al., 2014). It must be noted that these studies showing positive effects used osteopathic treatment (Herzhaft-Le Roy et al., 2017), rather than CST alone, and recruited preterm neonates (Cerritelli et al., 2013, 2015; Pizzolorusso et al., 2014), unlike Wellcome. Strengthening the knowledge base will not only help make the RD more evidence-based but will also clarify the need to conduct further research.

Other aspects, such as opposition to Wellcome by certain employees, the lack of presence of the physiotherapists in the daily clinical routine to promote Wellcome, and the issue of the prescription, were considered to be minor issues by the research team when compared to the more fundamental questions highlighted above. For this reason, their related list of tasks was organised in such way that it could be worked through in parallel. For example, to alleviate resistance to change, employee involvement will be further increased through regularly presenting preliminary results in the teams as iterations are completed (Freddy & Mbohwa, 2013). This employee involvement effect will be supported by the planned work shadowing and interprofessional discussions. Furthermore, additional information events and flyers should be held and distributed, respectively, and negative attitudes should be addressed individually.

Strengths and limitations

This pilot study's main strength lies in the innovative aspect of the therapeutic programme. Craniosacral therapy is rarely offered as a healthcare service at hospital and, to our knowledge, never in university hospitals in Switzerland. Hence, this is pioneering work and reveals potential for wider implementation. The methods used to develop the programme and the selected outcomes were also perceived as strengths. The participative approach used in the development phase fostered interprofessional collaboration and promoted acceptance of the programme. The diversity of outcome measures permitted a holistic evaluation of the pilot phase.

In contrast, the study's main limitation was a possible selection bias effect. Indeed, the recruitment strategy failed to include employees with negative attitudes towards Wellcome, which meant the reason for their opposition could not be determined explicitly. The same possibly applied with the recruited parents. It is conceivable that mainly parents who had pre-existing penchant for complementary and alternative medical treatment options accepted to participate.

Conclusions

In conclusion, the PDSA cycle completed in this pilot study paved the way for future implementation studies and showed that attitudes towards Wellcome were generally positive. Hence, proceeding with further piloting to collect additional data and gain more experience was recommended. Based on this result an easy-to-use project roadmap was devised, which retains the essence of the current pilot study's approach. That is, through proceeding with pilot phases, along with progressive improvement via more profound literature research, interprofessional exchanges and potential evidence generation, the programme will organically lower opposition and reach establishment within clinical routine. Moreover, the proposed methodology of iterative cycles matches the philosophy of PDSA very well, such that it can be easily embedded in that framework in future implementation studies.

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Original Research

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Clinical Determinants of Functional Capacity at Hospital Discharge in Patients with Heart Failure: A Secondary Observational Analysis

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Abstract

Introduction. Functional capacity is a key prognostic marker in heart failure (HF), yet it is frequently under-assessed at hospital discharge, and its clinical and demographic determinants during this critical period remain insufficiently characterized. This study aims to identify the clinical determinants of functional capacity at hospital discharge in patients with heart failure with reduced ejection fraction (HFrEF).

Methods. Cross-sectional observational study conducted at a tertiary center in Brazil with 140 patients. Functional capacity was assessed using the Veterans Specific Activity Questionnaire (VSAQ) and expressed in metabolic equivalents (METs). Sociodemographic, clinical (congestion score and visual analogue scale for dyspnea), and laboratory variables were collected. Multiple linear regression was used to identify independent predictors of age-adjusted METs.

Results. Mean age was 64.8 ± 14.0 years and mean left ventricular ejection fraction (LVEF) was 30.5 ± 6.5%. Mean functional capacity was 4.34 ± 3.43 METs, indicating severe impairment. In the multivariate analysis, NYHA functional class ($\beta = -1.033$; $p = 0.015$), congestion score ($\beta = -0.235$; $p = 0.015$), and dyspnea ($\beta = -0.232$; $p = 0.012$) were independent predictors of lower functional capacity. LVEF was not independently associated with functional capacity ($p = 0.583$).

Discussion. Functional capacity at discharge is determined

by symptom burden and functional class rather than LVEF alone. A substantial proportion of patients are discharged with significant functional impairment, underscoring the need for systematic functional assessment and early rehabilitation planning as part of heart failure care transition.

Keywords: Heart Failure, Functional Capacity, Hospital Discharge, Metabolic Equivalents, Nursing Assessment

Introduction

Heart failure (HF) represents a major global public health problem, associated with high rates of morbidity, mortality, and recurrent hospitalizations. Despite therapeutic advances, patients with HF, particularly those with reduced ejection fraction, continue to experience significant clinical and functional impairment (Savarese et al., 2023). In this context, functional capacity has emerged as a relevant prognostic marker, reflecting not only cardiovascular status but also the interaction among the musculoskeletal, respiratory, and metabolic systems.

Functional capacity, frequently expressed in metabolic equivalents (METs), constitutes an objective and clinically useful measure of exercise capacity (González-Mariscal et al., 2025). Reduced MET levels are associated with poorer quality of life, higher risk of rehospitalization, and increased mortality in patients with HF (Almeida-Neto et al., 2025). Therefore, assessment of this variable at the time of hospital discharge may provide important information for risk stratification and therapeutic planning.

Patients hospitalized for acute decompensated heart failure frequently exhibit significant deterioration in functional capacity, resulting from factors such as congestion, hypoperfusion, systemic inflammation, and physical deconditioning. Although clinical stabilization is the primary goal during hospitalization, many patients are discharged while still presenting with substantial functional limitations, which may negatively impact their short- and medium-term prognosis (Almeida-Neto et al., 2025; Silva et al., 2021).

Several clinical factors have been associated with functional capacity in patients with HF, including age, New York Heart Association (NYHA) functional class, and left ventricular ejection fraction (Bozkurt et al., 2021; Savarese et al., 2023). However, most studies focus on outpatient populations or clinically stable conditions, leaving a knowledge gap regarding the determinants of functional capacity specifically at the time of hospital discharge following an episode of decompensation.

The present study aims to characterize the clinical and demographic profile and to identify the clinical and demographic factors associated with functional capacity in patients hospitalized for heart failure with reduced ejection fraction at the time of hospital discharge.

Methods

Study design and setting

This is a cross-sectional observational study conducted in a public tertiary hospital in Brazil. Data were collected at hospital discharge between 2023-2025.

Participants

Eligible participants were adults (age >18 years) hospitalized for acute decompensated heart failure with reduced ejection fraction (HFrEF), defined as left ventricular ejection fraction (LVEF) < 40% on echocardiography performed during the index hospitalization. Patients on the heart transplant waiting list or with a life expectancy of less than 6 months documented in the medical records were excluded.

Variables

Sociodemographic variables

Sociodemographic variables included age

(years), sex (male/female), race/ethnicity (White, Brown, Black), and education level (low vs high). Heart failure–related variables included etiology (ischemic, hypertensive, Chagas disease, idiopathic), LVEF, New York Heart Association (NYHA) functional class (I–II vs III–IV), and hemodynamic profile (warm vs cold).

Clinical variables

Congestion score was assessed using a composite clinical score ranging from 0 to 22, calculated by summing scores from seven clinical signs and symptoms of heart failure: orthopnea (0–4), pulmonary crackles (0–4), elevated jugular venous pressure (0–4), peripheral edema (0–4), third heart sound (0–1), hepatojugular reflux (0–1), and NYHA functional class (1–4). Higher scores indicate greater degree of congestion (Rohde, et al. 2004).

Dyspnea was assessed using a simple visual analogue scale (VAS, 0–10), in which patients were asked to rate their current dyspnea sensation, with 0 indicating no dyspnea and 10 indicating the worst dyspnea imaginable.

Besides, body mass index (BMI, kg/m^2), systolic blood pressure (SBP, mmHg), diastolic blood pressure (DBP, mmHg), and heart rate (beats per minute, bpm) were collected. Laboratory measurements included hemoglobin (g/dL), creatinine (mg/dL), sodium (mEq/L), potassium (mEq/L), and urea (mg/dL).

Comorbidities were recorded as binary variables (yes/no) and included hypertension, diabetes mellitus, prior myocardial infarction, atrial fibrillation, depression, stroke, and chronic obstructive pulmonary disease.

Functional capacity

Functional capacity was assessed using the Veterans Specific Activity Questionnaire (VSAQ) (Domingues, et al. 2011). This instrument consists of 13 items designed to identify the level of daily physical activity associated with symptoms of cardiovascular disease, yielding a raw score ranging from 1 to 13; lower scores indicate greater functional limitation (Domingues et al., 2011). During the validation of the VSAQ, the authors observed that patient age and the VSAQ score were the most significant predictors of functional capacity expressed in METs, and accordingly developed a nomogram based on the equation METs = 4.7 + 0.97 × (VSAQ score) − 0.06 × (age) (Domingues et al., 2011), which converts the raw VSAQ score into an age-adjusted MET value. In the present study, two complementary measures of functional capacity were therefore analyzed: the raw VSAQ score (1–13 scale, unadjusted) and the age-adjusted MET value, calculated by applying the full nomogram equation above. Throughout the Results, "VSAQ" refers to the unadjusted score and "METs" refers to the age-adjusted value obtained from the nomogram.

Data sources and measurement

All variables were assessed at the time of hospital discharge by trained cardiovascular nurses as part of the primary trial data collection. Sociodemographic, clinical, laboratory, and functional capacity data were collected exclusively at this single discharge time point; admission-only values and longitudinal in-hospital trends (e.g., serial blood pressure or laboratory measurements) were not available for this secondary analysis.

Study size

The sample size was determined to provide an adequate number of observations for multiple linear regression analysis. Based on the recommendation of at least 10 participants per predictor variable, a minimum sample of 120 participants was considered sufficient for the planned model. A total of 140 participants were included, providing adequate statistical power for the exploratory analyses.

Statistical approach

All analyses were performed using R (R Core Team, 2024). Continuous variables were described as mean ± standard deviation (SD) or median (interquartile range, IQR) according to distribution. Categorical variables were described as frequency and proportion.

Bivariate associations between clinical variables and functional capacity were assessed using parametric tests, given the large sample size (n = 140) and the robustness of these methods under the central limit theorem.

Associations between METs and continuous predictor variables were assessed using the Pearson correlation coefficient (r). Between-group comparisons for binary variables (sex and hemodynamic profile) were performed using the independent samples t-test with Welch correction for unequal variances. For categorical variables with three or more groups (NYHA functional class and HF etiology), between-group differences were assessed using one-way analysis of variance (ANOVA).

When the overall ANOVA was statistically significant, post-hoc pairwise comparisons were conducted using the Tukey Honestly Significant Difference (HSD) test, which controls the familywise error rate across all pairwise comparisons simultaneously.

To identify independent predictors of functional capacity, a multiple linear regression model was fitted with log-transformed age-adjusted METs as the outcome variable. Logarithmic transformation was applied to approximate normality of the outcome distribution. All candidate predictors were entered simultaneously. Model fit was assessed by the coefficient of determination (R^2) and adjusted R^2.

Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki. The primary trial was approved by the Institutional Review Board, protocol number 5.568.868. All participants provided written informed consent prior to enrollment.

Results

A total of 140 patients were included, with a mean age of 64.8 ± 14.0 years, and 60.7% were male. Regarding race/ethnicity, 45.7% were White, 40.0% Brown, and 14.3% Black. Most participants had a low education level (58.6%).

The most common heart failure etiologies were ischemic (26.4%) and hypertensive (26.4%), followed by Chagas disease (23.6%) and idiopathic causes (16.4%). Mean left ventricular ejection fraction was 30.5 ± 6.5%. Most patients were classified as NYHA functional class I–II (66.4%), and 67.9% had a warm hemodynamic profile at discharge.

At discharge, the median congestion score was 2.0 (IQR 0.0–4.2), and mean dyspnea score was 4.3 ± 3.6. Mean body mass index was 26.7 ± 5.6 kg/m^2. Mean systolic and diastolic blood pressure were 114.2 ± 18.8 mmHg and 71.5 ± 14.2 mmHg, respectively, and mean heart rate was 77.5 ± 15.6 bpm.

Laboratory parameters showed a mean hemoglobin level of 12.9 ± 2.4 g/dL. Median creatinine and urea levels were 1.2 mg/dL (IQR 1.0–1.8) and 41.0 mg/dL (IQR 30.5–56.0), respectively. Mean sodium and potassium levels were 136.9 ± 4.7 mEq/L and 4.5 ± 3.3 mEq/L.

Comorbidities were common, with hypertension present in 72.9% of patients, followed by diabetes mellitus (44.3%), prior myocardial infarction (35.0%), atrial fibrillation (7.9%), depression (10.0%), stroke (9.3%), and chronic obstructive pulmonary disease (5.0%).

The mean raw VSAQ score was 4.34 ± 3.43, corresponding to a mean age-adjusted MET value of 5.02 ± 3.56, yielding a difference of +0.68 METs (Figure 1). No statistically significant difference was observed between the unadjusted and age-adjusted values ($p = 0.890$).

Bivariate associations between clinical variables and functional capacity are presented in Table 2. Among continuous variables, dyspnea showed the strongest inverse correlation with both raw and age-adjusted METs ($r = -0.540$ and $r = -0.498$, respectively; both $p < 0.001$), followed by congestion score ($r = -0.451$ and $r = -0.426$; $p < 0.001$) and LVEF ($r = +0.277$ and $r = +0.232$; $p < 0.001$). The association between age and functional capacity differed substantially between versions: while the correlation with the raw VSAQ score was weak ($r = -0.169$; $p = 0.046$), the correlation with age-adjusted METs was moderate and stronger ($r = -0.393$; $p < 0.001$), reflecting the age correction embedded in the nomogram.

Heart rate and creatinine were not significantly associated with either version of METs.

Table 1. Characteristics of the study sample.

Variable	Total (n = 140)
Sociodemographic characteristics	
Age (years), mean ± SD	64.8 ± 14.0
Male sex, n (%)	85 (60.7%)
Race/ethnicity, n (%)	
White	64 (45.7%)
Brown	56 (40.0%)
Black	20 (14.3%)
Education level, n (%)	
Low (illiterate or incomplete primary)	82 (58.6%)
High (complete primary or above)	58 (41.4%)
Heart failure characteristics	
HF etiology, n (%)	
Ischemic	37 (26.4%)
Hypertensive	37 (26.4%)
Chagas disease	33 (23.6%)
Idiopathic	23 (16.4%)
LVEF (%), mean ± SD	30.5 ± 6.5
NYHA class, n (%)	
I–II	93 (66.4%)
III–IV	47 (33.6%)
Hemodynamic profile, n (%)	
Warm	95 (67.9%)
Cold	45 (32.1%)
Clinical parameters	
Congestion score, median (IQR)	2.0 (0.0–4.2)
Dyspnea VAS, mean ± SD	4.3 ± 3.6
BMI (kg/m^2), mean ± SD	26.7 ± 5.6
SBP (mmHg), mean ± SD	114.2 ± 18.8
DBP (mmHg), mean ± SD	71.5 ± 14.2
Heart rate (bpm), mean ± SD	77.5 ± 15.6
Laboratory parameters	
Hemoglobin (g/dL), mean ± SD	12.9 ± 2.4
Creatinine (mg/dL), median (IQR)	1.2 (1.0–1.8)
Sodium (mEq/L), mean ± SD	136.9 ± 4.7
Potassium (mEq/L), mean ± SD	4.5 ± 3.3
Urea (mg/dL), median (IQR)	41.0 (30.5–56.0)
Comorbidities	
Hypertension, n (%)	102 (72.9%)
Diabetes mellitus, n (%)	62 (44.3%)
Prior MI, n (%)	49 (35.0%)
Atrial fibrillation, n (%)	11 (7.9%)
Depression, n (%)	14 (10.0%)
Stroke, n (%)	13 (9.3%)
COPD, n (%)	7 (5.0%)

Education: "Low" = illiterate or incomplete primary education; "High" = complete primary education or above. NYHA: "Compensated" = NYHA I–II; "Advanced" = NYHA III–IV. Hemodynamic profile: "Warm" = warm-dry + warm-wet; "Cold" = cold-wet + cold-dry. HF = heart failure; BMI = body mass index; COPD = chronic obstructive pulmonary disease; DBP = diastolic blood pressure; IQR = interquartile range; LVEF = left ventricular ejection fraction; SD = standard deviation; MI = myocardial infarction; NYHA = New York Heart Association; SBP = systolic blood pressure; VAS = visual analogue scale; bpm = beats per minute.

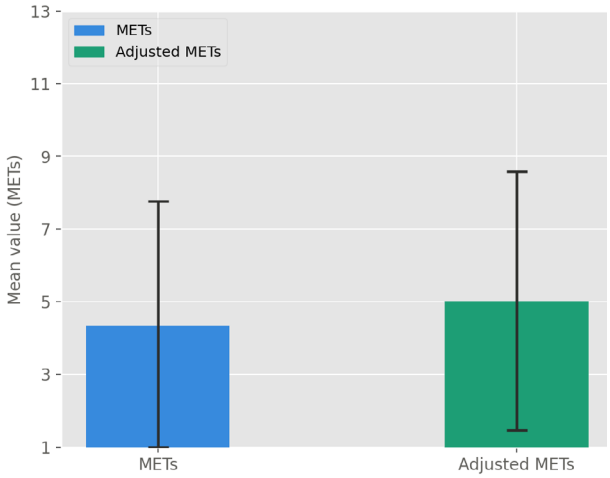


Figure 1. Raw and age-adjusted METs at hospital discharge in patients with heart failure, Brazil, 2026.

Table 2. Pearson correlations between continuous clinical variables and functional capacity.

Variable	r (VSAQ score)	p	r (METs age-adj.)	p
Dyspnea VAS	−0.540	< 0.001	−0.498	< 0.001
Congestion score	−0.451	< 0.001	−0.426	< 0.001
Age (years)	−0.169	0.046	−0.393	< 0.001
LVEF (%)	+0.277	< 0.001	+0.232	0.006
Creatinine (mg/dL)	−0.127	0.136	−0.125	0.143
Heart rate (bpm)	−0.098	0.251	−0.054	0.527

r = Pearson correlation coefficient. n = 140. VSAQ score = raw activity score (1–13 scale, unadjusted). METs age-adjusted = 4.7 + 0.97 × VSAQ − 0.06 × age (VSAQ nomogram). Parametric tests used given n = 140 (central limit theorem). Variables sorted by magnitude of correlation with the raw VSAQ score. Highlighted rows and bold values = p < 0.05. LVEF = left ventricular ejection fraction; METs = metabolic equivalents; VAS = visual analogue scale; VSAQ = Veterans Specific Activity Questionnaire.

Sex and hemodynamic profile were not significantly associated with functional capacity (table 3). Male and female patients presented similar raw VSAQ scores (4.67 ± 3.60 vs 3.84 ± 3.10; mean difference +0.83, 95% CI: −0.29 to 1.96; p = 0.160) and age-adjusted METs (5.39 ± 3.74 vs 4.46 ± 3.22). Similarly, no significant difference was observed between patients with warm and cold hemodynamic profiles in either raw VSAQ (4.29 ± 3.46 vs 4.44 ± 3.39; mean difference −0.15, 95% CI: −1.36 to 1.06; p = 0.81) or age-adjusted METs (4.95 ± 3.58 vs 5.19 ± 3.55).

Table 3. Functional capacity by binary clinical variables, t-test comparisons.

Variable	Group	n	VSAQ score mean ± SD	METs age-adj. mean ± SD	Mean difference (95% CI)	p
Sex	Male	85	4.67±3.60	5.39 ± 3.74	0.83 (−0.29 to 1.96)	0.160
	Female	55	4.46 ± 3.22	4.46 ± 3.22		
Hemodynamic profile	Warm	95	4.29 ± 3.46	4.95 ± 3.58	−0.15 (−1.36 to 1.06)	0.810
	Cold	45	4.44 ± 3.39	5.19 ± 3.55		

NYHA functional class was strongly associated with both raw and age-adjusted METs (ANOVA: F = 33.88 and F = 26.71; p < 0.001). Post-hoc analysis revealed that NYHA class I was significantly different from all other classes (all p ≤ 0.006).

HF etiology was also significantly associated with functional capacity (ANOVA: F = 4.36, p = 0.006; F = 4.89, p = 0.003 for age-adjusted). Despite overall significance, post-hoc comparisons did not reach statistical significance, with the largest difference observed between Chagas disease and idiopathic etiology (diff = −3.06 raw, p = 0.089; diff = −3.36 adj, p = 0.062), suggesting a trend toward lower functional capacity in Chagas patients.

Table 4. Functional capacity by categorical clinical variables, one-way ANOVA.

Variable	Group (n)	VSAQ score mean ± SD	F	METs age-adj. mean ± SD	F	df	p
NYHA class	Class I (33)	8.18 ± 4.09	33.88	8.77 ± 4.24	26.71	3, 136	< 0.001
	Class II (60)	3.82 ± 1.85		4.44 ± 2.11			
	Class III (38)	2.21 ± 1.44		3.01 ± 1.62			
	Class IV (9)	2.78 ± 3.87		3.67 ± 4.08			
HF etiology	Ischemic (37)	4.70 ± 3.49	4.36	5.00 ± 3.50	4.89	3, 136	0.006
	Hypertensive (37)	4.86 ± 3.54		5.71 ± 3.62			
	Chagas (33)	2.73 ± 1.51		3.29 ± 1.69			
	Idiopathic (23)	5.78 ± 4.57		6.65 ± 4.61			

Three predictors were independently associated with lower functional capacity after adjusting for all other variables in the model (table 5). Higher NYHA functional class was associated with lower METs (β = −1.033; 95% CI: −1.866 to −0.201; p = 0.015), indicating that each additional NYHA class was associated with a reduction of approximately 1.0 METs in age-adjusted functional capacity.

Higher congestion score (β = −0.235; 95% CI: −0.424 to −0.046; p = 0.015) and higher dyspnea (β = −0.232; 95% CI: −0.412 to −0.051; p = 0.012) were also independently associated with lower functional capacity.

LVEF was not a significant independent predictor after adjusting for the other variables (β = −0.023; p = 0.583), suggesting that its effect on functional capacity is largely mediated by symptom severity. HF etiology was not significantly associated with functional capacity when compared to the ischemic reference category (all p > 0.21), although a trend toward lower METs was observed in patients with Chagas disease (β = −0.695; p = 0.306).

Table 5. Multiple linear regression, independent predictors of functional capacity (METs age-adjusted).

Predictor	β	95% CI	SE	t	p-value
R^2 = 0.374 | Adjusted R^2 = 0.341 F (7, 132) = 11.27 | p < 0.001					
NYHA class (ordinal)	−1.033	(−1.866, −0.201)	0.421	−2.455	**0.015**
LVEF (%)	−0.023	(−0.108, +0.061)	0.043	−0.550	0.583
Congestion score	−0.235	(−0.424, −0.046)	0.095	−2.464	**0.015**
Dyspnea VAS	−0.232	(−0.412, −0.051)	0.091	−2.537	**0.012**
HF etiology					
Hypertensive vs Ischemic	+0.527	(−0.758, +1.811)	0.649	+0.811	0.419
Chagas vs Ischemic	−0.695	(−2.033, +0.642)	0.676	−1.028	0.306
Idiopathic vs Ischemic	+0.943	(−0.539, +2.425)	0.749	+1.258	0.210

Outcome: METs age-adjusted (nomogram: 4.7 + 0.97 × VSAQ − 0.06 × age). β = unstandardized regression coefficient; SE = standard error; 95% CI computed using t-distribution (df = 132). Etiology entered as dummy variables with ischemic etiology as reference category. Highlighted rows and bold values = p < 0.05. LVEF = left ventricular ejection fraction; METs = metabolic equivalents; NYHA = New York Heart Association; VAS = visual analogue scale

Discussion

The present study identified that functional capacity at hospital discharge in patients with heart failure with reduced ejection fraction (HFrEF) is not independently determined by left ventricular ejection fraction (LVEF), but rather by a constellation of clinical determinants reflecting multisystemic reserve, particularly symptom burden, including dyspnea and congestion, and NYHA functional class.

These findings align with the contemporary literature in demonstrating that hemodynamic stabilization and improvement in systolic function do not necessarily translate into recovery of cardiorespiratory fitness at the point of care transition (Bozkurt et al., 2021; Savarese et al., 2023).

The mean age-adjusted MET value observed in this sample (5.02 ± 3.56) indicates a state of severe functional impairment, placing most patients below the critical threshold of 5 METs required for independent performance of basic activities of daily living. Savarese et al. (2023) have shown that cardiorespiratory fitness is a more reliable predictor of survival than LVEF itself, given that each 1-MET increment is associated with up to a 15% reduction in all-cause mortality. The mean value observed here therefore suggests that these patients are discharged at a "frailty threshold," where diminished metabolic reserve predisposes them to adverse clinical outcomes and early rehospitalization.

The transition from tertiary care to the home setting represents the period of greatest patient vulnerability, frequently referred to as the "vulnerable risk phase." Our findings demonstrate that severe functional limitation amplifies these risks, as patients with low exercise reserve experience greater difficulty distinguishing between fatigue attributable to physical deconditioning and early signs of new decompensation (Sethares et al., 2023).

Dyspnea, assessed by visual analogue scale (VAS), showed the strongest correlation with METs ($r = -0.540$), suggesting that the patient's subjective perception serves as a sensitive indicator of cardiopulmonary integrity. Correa Nascimento et al. (2023) recently reported that persistent residual dyspnea at discharge is an independent predictor of adverse events within 30 days.

Our data add a physiological dimension to this observation, indicating that dyspnea at discharge is not merely a risk marker, but a direct reflection of objectively impaired cardiorespiratory fitness, possibly compounded by ventilatory mechanics compromised by persistent subclinical congestion. Although direct measurement of peak oxygen uptake (peak VO_2) via cardiopulmonary exercise testing remains the gold standard for assessing functional capacity, this approach is often impractical in the acute post-discharge setting due to equipment and staffing requirements. MET-based estimation tools such as the VSAQ offer a more feasible and sustainable alternative for routine clinical use, and Bozkurt et al. (2021) have noted that such estimates show clinically acceptable correlation with functional performance and quality of life.

Among the most notable findings of this study is the independent association between congestion score and functional capacity. This suggests that residual congestion exerts a bimodal detrimental effect: first, by reducing pulmonary compliance and increasing the work of breathing; and second, by inducing peripheral tissue edema that impairs oxygen and nutrient diffusion to skeletal myocytes (Pirrota et al., 2021).

This mechanism may partly account for the absence of an independent association between LVEF and functional capacity in the multivariate model ($p = 0.583$), a phenomenon referred to as the "functional paradox." Li et al. (2025) demonstrated that physical performance in HFrEF is predominantly governed by non-cardiac mechanisms, including mitochondrial dysfunction and structural alterations of skeletal muscle, independent of pump function. Accordingly, improvements in cardiac contractility may occur while the peripheral "motor", skeletal muscle, remains in a state of functional failure, limiting oxygen consumption during exertion (Li et al., 2025).

Regarding NYHA functional class, a reduction of approximately 1.0 MET per class increment was observed. Notably, however, the plateau of low functional capacity identified across classes II, III, and IV suggests that a recent episode of acute decompensation exerts a leveling effect on functional reserve. This pattern indicates that, at the time of discharge, even patients reporting symptomatic improvement share a common substrate of severe deconditioning

with those who remain more clinically limited.

Finally, the trend toward worse functional performance observed in patients with Chagas disease etiology reinforces the aggressiveness of this condition, which combines extensive myocardial fibrosis with autonomic instability and persistent inflammation (Marcondes-Braga et al., 2021). Taken together, these findings underscore that objective assessment of functional capacity at hospital discharge should be integrated as an essential clinical parameter. Identifying this state of functional frailty enables individualized care planning, supports the early prescription of cardiovascular rehabilitation, and optimizes the transition to home-based self-care (Wu et al., 2024).

Practical implications

These findings have direct implications for clinical practice. First, the identification of residual dyspnea and congestion as independent determinants of functional capacity at discharge reinforces that complete decongestion, rather than only hemodynamic stabilization, should be the one important therapeutic goal prior to discharge in patients with HFrEF.

Second, the results support the routine incorporation of functional capacity assessment into the discharge plan. The VSAQ is a brief, equipment-free instrument that can be readily administered by professional healthy, enhancing risk stratification and informing decisions regarding rehabilitation referral and post-discharge follow-up intensity.

Third, although LVEF remains a cornerstone of HFrEF diagnosis and management, its lack of independent association with functional capacity after adjustment for symptom burden suggests that echocardiographic parameters alone may not fully capture a patient's functional status at the time of discharge. Structured functional assessment should therefore complement, rather than replace, traditional clinical markers in discharge planning.

Finally, the trend toward lower functional capacity in patients with Chagas disease etiology suggests this subgroup may benefit from more intensive post-discharge monitoring, given the distinctive burden of autonomic dysfunction and progressive myocardial damage associated with this condition.

Limitations

Some limitations should be acknowledged. First, the cross-sectional design cannot provide causal inference, as all measures reflect concurrent assessments at the time of discharge. Second, the single-center sample may limit generalizability to other healthcare settings or populations with distinct sociodemographic profiles. Third, functional capacity was estimated using the VSAQ rather than cardiopulmonary exercise testing; although the VSAQ is validated and feasible in hospitalized patients, self-report measures may not fully capture true physiological limits, particularly in those recently recovering from acute decompensation.

Additionally, the population profile of this sample may limit generalizability. Nearly 24% of patients had HF related to Chagas disease, an etiology that is uncommon outside Latin America; future studies should evaluate whether the impact of etiology on functional capacity varies according to the prevalence of different HF etiologies across regions. Similarly, nearly 67% of the sample was in NYHA class I or II, a distribution that may not reflect populations with a higher burden of advanced disease, potentially limiting extrapolation of these findings to more symptomatic cohorts. Finally, this analysis focused on a predefined set of clinical variables; other potentially relevant factors, such as chronic obstructive pulmonary disease, depression, cognitive impairment, discharge hemoglobin level, and in-hospital mobilization practices, were not modeled and may independently influence functional capacity. Future studies should explore these variables, alongside the mobilization and rehabilitation strategies applied during hospitalization, as their inclusion may substantially refine risk stratification at discharge.

Conclusion

In patients hospitalized for HFrEF, functional capacity at discharge is primarily determined by symptom burden, particularly dyspnea, residual congestion, and NYHA functional class, rather than by LVEF alone. A substantial proportion of patients are discharged with severe functional impairment, revealing a clinically meaningful gap between hemodynamic stabilization and true functional recovery.

This dissociation has direct implications for care transition, as many patients return home with limited capacity to perform basic activities and engage in adequate self-care. These findings support the systematic incorporation of functional capacity assessment into discharge planning, alongside traditional clinical parameters. Identifying residual symptoms and functional limitation at this critical juncture may guide more targeted interventions, including optimization of decongestion, early cardiovascular rehabilitation, and individualized care planning, ultimately moving the therapeutic goal in heart failure beyond stabilization toward functional recovery.

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Review

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Home-Based Educational Strategies for Informal Caregivers of People with Psychosis: A Scoping Review

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Abstract

Introduction. According to the World Health Organization, the burden of mental disorders is steadily increasing, with significant health and socioeconomic impacts worldwide. People living with psychosis often face challenges in daily functioning, employment, and social interactions, which frequently leads them to live with their families. In this context, informal caregivers play a crucial role in supporting the therapeutic and rehabilitative process. The aim of this study is to explore and map the current literature on home-based educational strategies for informal caregivers of people with psychosis.

Materials and Methods. A scoping review was conducted following Arksey and O'Malley's framework and the PCC approach. Searches were performed in major biomedical databases between April and June 2024. Eligible studies involved caregivers of individuals with psychosis, were written in English, Spanish, or French, and reported nurse-led educational interventions, outcomes, or experiences related to mental health care. Screening and analysis were independently performed by two reviewers.

Results. Educational strategies targeting caregivers offer significant clinical and health benefits for individuals with psychosis, including reduced relapse rates and disability, improved treatment adherence, greater knowledge, and enhanced quality of life. Caregivers who often experience knowledge gaps benefit from educational interventions

that support skill development, alleviate caregiver burden, and promote their own well-being. Key facilitators of these interventions include the use of supportive materials, a calm and respectful environment, active listening, a transcultural approach, and clearly defined strategies. Major barriers include stigma, misinformation, and financial hardship experienced by families.

Discussion. Through health education, nurses play a key role in enhancing the health and well-being of the entire family unit. Raising community awareness and promoting health promotion and disease prevention initiatives are essential strategies to reduce morbidity and mortality rates.

Keywords: Psychosis, Caregivers, Health Education, Education, Home Care

Introduction

Mental disorders, syndromes characterized by clinically significant abnormalities in cognitive functions, emotional regulation, or behavior, cause considerable difficulties in daily activities (ADLs), as well as at social and occupational levels, affecting individuals of both genders and all age groups (Chaudhury et al., 2006; Iliou et al., 2024; WHO, Mental Health, 2022). The onset of psychosis, often related to exposure to various risk factors and traumatic/stressful experiences, occurs mainly in late adolescence and early adulthood, around the age of 20 (Brasso et al., 2021; Hua et al., 2021; NIMH, Understanding Psychosis, 2023). According to the World Health Organization, mental disorders are increasing worldwide, with significant public health, social, and economic consequences (World Health Organization, 2025). In 2021, anxiety and depressive disorders were the most prevalent mental health conditions, affecting an estimated 359.2 million and 332.4 million people, respectively, and representing 63.1% of all mental disorders worldwide (Zhang et al., 2026). Mental disorders currently rank as the fifth leading cause of global disability-adjusted life years, rising from twelfth place in 1990; anxiety disorders, depressive disorders, and schizophrenia are among the main contributors (Santomauro et al., 2026).

Informal caregivers (ICs) are family members who provide ongoing care and support to relatives affected by illness or disability without receiving financial compensation (Istituto Superiore di Sanità, 2021), may experience psychological stress, or burden, resulting from the physical and emotional overload of daily responsibilities, social pressures, and financial difficulties (Gutiérrez-Maldonado et al., 2005). Therefore, it is essential to support, inform, and involve them in the care process, considering the overall well-being of the family unit (Bucci et al., 2016; McFarlane, 2016).

Therapeutic outcomes often depend not only on the nurse's knowledge and skills but also on their ability for introspection and self-awareness (Stuart, 2012). Communication skills, such as active listening and the appropriate use of verbal and non-verbal language, are fundamental for delivering effective and truly person-centred nursing care (Varcarolis, 2010). To achieve better health outcomes, the caregiver's involvement is essential; therefore, it is crucial to consider them as an integral part of the care process, on an equal footing with the patient (Tasseron-Dries et al., 2023). Home psychiatric care is a feasible and cost-effective alternative to hospitalization (Waldmann et al., 2025). Community psychiatric nurses play a key role in assessing both mental and physical health needs, thereby supporting holistic care and facilitating access to specialized services when appropriate (Litvin & Bliss, 2024; St John et al., 2020). Their role involves assessing psychopathology and developing interventions that include educating patients about medications, mental disorders, and coping skills to help them remain within the community (Hellwig, 1993). Although the importance of home-based care in psychiatric treatment is widely recognized, the existing literature remains heterogeneous in identifying which

interventions are most effective in improving patient health outcomes and enhancing caregiver competencies, while simultaneously reducing caregiver burden. The aim of this scoping review is to map the literature on currently accessible educational strategies for ICs of individuals with psychosis at home educational interventions, interventions aimed at reducing caregiver burden, and multidisciplinary interventions in home care for ICs, evaluating their effectiveness in terms of clinical and health outcomes for both patients and caregivers.

This review aims to address the following research questions:

- (RQ1) What educational strategies are available for ICs of individuals with psychosis in home settings?
- (RQ2) What clinical and health outcomes are expected for the individual with psychosis?
- (RQ3) What health outcomes are expected for the ICs?
- (RQ4) What are the main barriers and facilitators in the implementation of these interventions?
- (RQ5) What are the implications for nursing practice?

Methods

Study design

This study was designed as a scoping review, conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews (Peters et al., 2020a), and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) provided as Supplementary File 1 (Tricco et al., 2018).

Eligibility criteria

The inclusion criteria comprised studies involving caregivers of individuals with psychosis, written in English, Spanish, or French. Meta-analyses, literature reviews, observational studies, experimental studies, qualitative studies, and editorials are considered eligible. Eligible studies included those in which nurses delivered one or more educational interventions, as well as those reporting clinical and/or health outcomes for individuals with psychosis and/or their caregivers. Studies exploring experiences and expectations regarding mental health services were also considered. Conversely, studies focusing on organic or substance-induced psychoses, those not addressing the specific research questions, and study protocols were excluded from the review. The search covered the period from 2014 to 2024 to ensure the inclusion of studies reflecting the most recent knowledge and technological advancements in the field

Search strategies

A systematic literature search was conducted between April and June 2024 using major biomedical databases, including PubMed, CINAHL, Embase, and PsycInfo. The search strategy is reported in the Supplementary File 2. Search strings were developed with the support of the University Library System, University of Milan, Milan, Italy, including the terms "psychosis," "caregiver," "health education," "education," and "home care" and their synonyms.

The search included various study designs: meta-analyses, literature reviews, observational studies, experimental studies, qualitative studies, and editorials. Search strategies were developed according to the Joanna Briggs Institute guidelines (Peters et al., 2020b), using the Population, Concept, and Context framework as a reference.

Study selection process

Following the JBI guidelines, the study selection process was conducted by two authors (ER and SA). Titles and abstracts were independently screened to identify potentially relevant studies. The full texts of eligible articles were then assessed according to the inclusion criteria. Any disagreements regarding study inclusion were resolved through discussion with a third author (SU).

Data Extraction

An Excel-based data extraction table, which included predefined variables for extraction, was prepared before conducting the review.

The table was compiled independently by the two reviewers and includes details such as title/authors/year of publication/country, applied methodology, objective, population/sample characteristics, interventions/data collection tools, outcomes, and keywords.

Summary of Results

Extracted data were synthesized and presented through a narrative review. Tables and graphs were used to represent the information.

Risk of Bias

Scoping reviews are designed to provide an overview of the available evidence, without necessarily conducting a methodological quality assessment or a risk of bias evaluation. Therefore, the sources included in this review were not subjected to a rigorous critical analysis of bias risk (Tricco et al., 2018).

Results

Selection of source of evidence

The initial search yielded 379 records. After removing 164 duplicates, 215 articles remained for screening. Title and abstract screening led to the exclusion of 179 articles: 163 due to irrelevant outcomes, 10 due to non-eligible populations, and 6 due to inappropriate study designs.

A total of 36 full-text articles were assessed for eligibility. Of these, 31 met the inclusion criteria. 3 articles were excluded for not addressing the research questions, and 2 were excluded due to an ineligible population. An additional 3 articles relevant to the research questions were identified through a supplementary search, assessed for eligibility, and included in the review. The screening process is illustrated in the PRISMA Flow Diagram (Page et al., 2021) Figure 1.

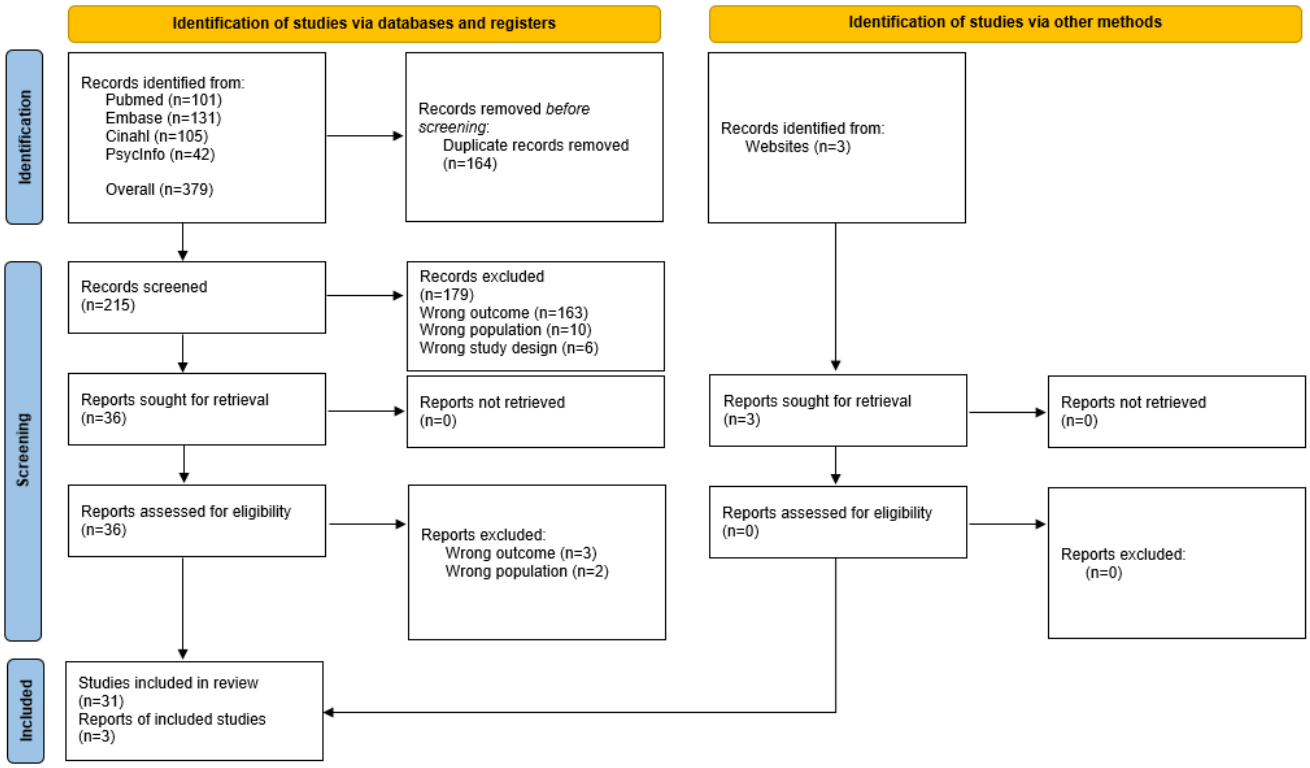


Figure 1. PRISMA Flowchart of the study.

Characteristics of the included studies

The 34 selected articles comprised the following study designs: 1 meta-analysis (3%), 3 literature reviews (9%), 10 observational studies (29%), 9 qualitative studies (27%), 10 experimental studies (29%), and 1 editorial (3%). All studies were published as journal articles, with 6 appearing in

nursing journals (18%) and 28 in journals related to other healthcare disciplines (82%).

A total of 23.5% of the articles were published between 2013 and 2018, while the remaining 76.5% were published between 2019 and 2024. The studies were conducted in the following geographic areas, as shown in Figure 2: 15 studies in Europe (44%), 14 studies in Asia (41%), 2 studies in the Middle East (6%), 2 studies in North America (6%), and 1 study in Africa (3%).

Based on the World Bank income classification (Metreau et al., 2024), 22 studies were conducted in high-income countries (64%), 7 in upper-middle-income countries (21%), and 5 in lower-middle-income countries (15%). The characteristics of the included documents are reported in Table 1.

A summary of the findings addressing the research questions is provided in Supplementary File 3.

RQ1: What educational strategies are available for ICs of individuals with psychosis in home settings?

The educational strategies were grouped according to the intervention model used.

Family Psychoeducation

Across the included studies, home-based psychoeducational interventions were primarily aimed at reducing environmental stress and improving family functioning by strengthening communication, problem-solving, and coping skills, while also addressing caregiver anxiety and burden. These interventions supported adherence to therapeutic and rehabilitative pathways through education on the disorder, available services, and strategies to create a supportive family environment (Gomis et al., 2017a; Kidd SA et al., 2018a; Kumar D et al., 2019a; Lyles et al., 2023a). Several programs also sought to reduce stigma, dispel false beliefs, and address maladaptive family dynamics, including high levels of emotional involvement and expressed emotion, using home visits, group sessions, manuals, illustrations, role-play, and quizzes (Cechnicki A et al., 2023; Davtian & Scelles, 2014; Kidd SA et al., 2018a; Kumar D et al., 2019a; Lyles et al., 2023a). Overall, the most frequently adopted strategies in home-based sessions included psychoeducation, emotional support, coping-skills training, and guidance to

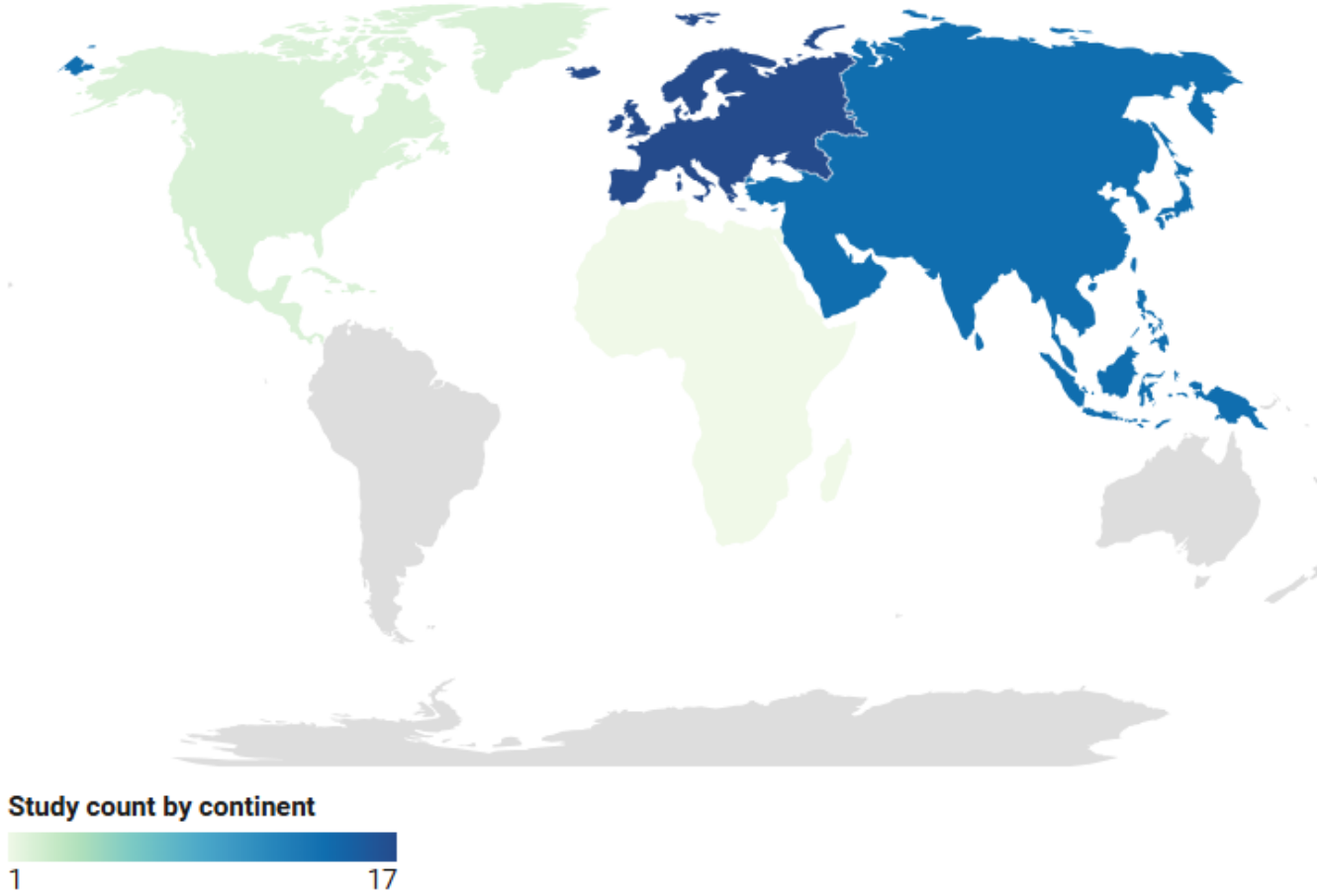


Figure 2. Geographical Distribution of the Included Studies.

Table 1. Characteristics of studies included.

Included articles (n= 34)				
	N	%	Notes	Authors
Year of publication				
(from 2013 to 2018)	8	23,5%		Alka et al.; Davtian and Lamotte; Davtian and Scelles; Gomis et al.; Grácio et al.; Kidd et al; Lavis et al.; Malakouti et al.
(from 2019 to 2024)	26	76,5%		Alston et al.; Bademli et al; Barranha et al.; Basavaraju et al.; Budiarto et al.; Cechnicki et al.; Chen et al.; Chuttoo et al.; Ferentinos et al.; Hode et al.; Ilmy et al.; Iswanti et al. (2023); Iswanti et al. (2024); Kim and Park; Kumar et al.; Lyles et al.; Mathew and Mathias; Moreno-Alonso et al.; O'Neill et al.; Onwumere et al.; Oyelade et al.; Peng et al.; Tessier et al.; Tramier et al.; Widiyawati et al.; Yasuma et al.
Geographic area				
Africa	1	3%		Oyelade et al.
Asia	14	41%		Alka et al.; Basavaraju et al.; Budiarto et al.; Chen et al.; Ilmy et al.; Iswanti et al. (2023); Iswanti et al. (2024); Kim and Park; Kumar et al.; Lyles et al.; Mathew and Mathias; Peng et al.; Widiyawati et al.; Yasuma et al.
Europe	15	44%		Barranha et al.; Cechnicki et al.; Chuttoo et al.; Davtian and Lamotte; Davtian and Scelles; Ferentinos et al.; Gomis et al.; Grácio et al.; Hode et al.; Lavis et al.; Moreno-Alonso et al.; O'Neill et al.; Onwumere et al.; Tessier et al.; Tramier et al.
Middle East	2	6%		Bademli et al; Malakouti et al.
North America	2	6%		Alston et al.; Kidd et al.
Country's economy				
Low middle income	5	15%		Alka et al.; Basavaraju et al.; Kumar et al.; Mathew and Mathias; Oyelade et al.
High middle income	7	21%		Budiarto et al.; Ilmy et al.; Iswanti et al. (2023); Iswanti et al. (2024); Lyles et al.; Malakouti et al.; Widiyawati et al.
High income	22	64%		Alston et al.; Bademli et al; Barranha et al.; Cechnicki et al.; Chen et al.; Chuttoo et al.; Davtian and Lamotte; Davtian and Scelles; Ferentinos et al.; Gomis et al.; Grácio et al.; Hode et al.; Kidd et al; Kim and Park; Lavis et al.; Moreno-Alonso et al.; O'Neill et al.; Onwumere et al.; Peng et al.; Tessier et al.; Tramier et al.; Yasuma et al.
Field of the journal				
Nursing	6	18%		Alka et al.; Alston et al.; Ilmy et al.; Iswanti et al. (2023); Iswanti et al. (2024); Kim and Park.
Others	28	82%	Medicine, Psichiatry, Psichology, Public health	Bademli et al.; Barranha et al.; Basavaraju et al.; Budiarto et al.; Cechnicki et al.; Chen et al.; Chuttoo et al.; Davtian and Lamotte; Davtian and Scelles; Ferentinos et al.; Gomis et al.; Grácio et al.; Hode et al.; Kidd et al.; Kumar et al.; Lavis et al.; Lyles et al.; Malakouti et al.; Mathew and Mathias; Moreno-Alonso et al.; O'Neill et al.; Onwumere et al.; Oyelade et al.; Peng et al.; Tessier et al.; Tramier et al.; Widiyawati et al.; Yasuma et al.
Type of publication				
Newspaper article	34	100%		Alka et al.; Alston et al.; Bademli et al.; Barranha et al.; Basavaraju et al.; Budiarto et al.; Cechnicki et al.; Chen et al.; Chuttoo et al.; Davtian and Lamotte; Davtian and Scelles; Ferentinos et al.; Gomis et al.; Grácio et al.; Hode et al.; Ilmy et al.; Iswanti et al. (2023); Iswanti et al. (2024); Kidd et al.; Kim and Park; Kumar et al.; Lavis et al.; Lyles et al.; Malakouti et al.; Mathew and Mathias; Moreno-Alonso et al.; O'Neill et al.; Onwumere et al.; Oyelade et al.; Peng et al.; Tessier et al.; Tramier et al.; Widiyawati et al.; Yasuma et al.
Study design				
Meta-analysis	1	3%	3%	Kim and Park
Literature reviews	3	9%	9%	Gomis et al.; Iswanti et al. (2023); Lyles et al.
Observational	10	29%	29%	Alka et al.; Alston et al.; Barranha et al.; Basavaraju et al.; Cechnicki et al.; Chuttoo et al.; Davtian and Lamotte; Davtian and Scelles; Hode et al.; Widiyawati et al.
Qualitative	9	27%		Chen et al.; Ferentinos et al.; Ilmy et al.; Lavis et al.; Mathew and Mathias; O'Neill et al.; Oyelade et al.; Peng et al.; Tramier et al.
Experimental design	10	29%		Bademli et al.; Budiarto et al.; Grácio et al.; Iswanti et al. (2024); Kidd et al; Kumar et al.; Malakouti et al.; Moreno-Alonso et al.; Tessier et al.; Yasuma et al.
Development and validation of measurement tools, Letters, Editorial	1	3%		Onwumere et al.

help families manage emotional involvement more effectively (Davtian & Scelles, 2014; Kidd SA et al., 2018a; Kumar D et al., 2019a).

Cognitive Behavioral Therapy (CBT)

According to Gomis et al., CBT is the most recommended treatment in guidelines for psychotic disorders (Gomis et al., 2017a). The "Culturally Adapted CBT for Psychosis" (CaCBTp), applied in Pakistan using the Kingdon and Turkington model, integrated family involvement with the treatment of anxiety and depression, as well as strategies to manage symptoms and improve coping mechanisms (Lyles et al., 2023a).

Cognitive Rehabilitation

Cognitive rehabilitation aimed to enhance cognitive functions such as memory, attention, and reasoning (Lyles et al., 2023a). The program by Kumar et al. proposed progressively more complex exercises (Kumar D et al., 2019a). The "Cognitive Adaptation Training" (CAT) by Kidd et al. provided caregivers with a manual containing support materials, worksheets, and explanatory DVDs to improve disorder management and collaboration with healthcare professionals (Kidd SA et al., 2018a). This intervention was compared to independent reading of the book Complete Family Guide to Schizophrenia by Mueser and Gingerich (Kidd SA et al., 2018a), which explores practical strategies for quality of life and relapse prevention, and was also used in another study (Davtian & Scelles, 2014).

Community-Based Support Interventions

In South Asia, interventions were based on structured needs assessments, psychoeducation, self-care strategies, and reducing social stigma (Lyles et al., 2023a). In the United Kingdom, Community Mental Health Teams (CMHTs) operated in community settings to provide integrated support (Cechnicki A et al., 2023).

Family Empowerment

Iswanti et al. define family empowerment as a process to enhance autonomy and the ability to achieve personal and social goals. The intervention focused on increasing cultural sensitivity and using strategies such as narrative therapy and self-learning, emphasizing the needs for independence, acceptance of the disorder, and social inclusion(Iswanti DI et al., 2024a). In a more recent study by the same researcher, an integrated holistic model focused on the interaction between family and community dynamics, promoting stress management and coping with daily challenges (Lavis A et al., 2015).

Combined Interventions

The reviewed studies showed that multidisciplinary home-based services such as Early Intervention Services (EIS) and Crisis Resolution Home Teams (CRHTs) combined family and individual interventions during relapse, integrating pharmacological treatment with psychological and psychosocial approaches, including cognitive behavioural therapy and social skills training, to manage crises and improve social functioning (Malakouti et al., 2016a; Yasuma et al., 2024a). Psychoeducation emerged as the intervention model most frequently integrated with other approaches, such as CBT, psychosocial interventions, and nursing care (Alston M et al., 2019a; Basavaraju V et al., 2022a; Budiarto et al., 2019a; Chen et al., 2019; Iswanti DI et al., 2024a; Mathew & Mathias, 2024). Within this framework, nurses played a relevant role through home visits, during which they provided education to patients and caregivers, monitored symptoms and treatment side effects, and ensured emergency support when needed (Ilmy et al., 2022). In addition, evidence from a meta-analysis supported the effectiveness of family-focused emotional support and problem-solving strategies, delivered through approaches such as family-to-family support, narrative practice, film therapy, psychoeducation, emotional regulation, and peer-assisted education (Widiyawati W et al., 2020).

RQ2: What clinical and health outcomes are expected for the individual with psychosis?

The clinical outcomes identified from the document analysis were: reduction in relapses and hospitalizations, decrease in symptomatology, improvement in recognizing relapses, symptom management, and increased awareness of the disorder, greater adherence to the therapeutic-rehabilitative treatment, and

reduction in suicide attempts. The results will be analyzed in detail below.

The retrospective study by Chuttoo et al. highlighted a reduction in relapses and in the use of acute care services after the intervention, including a decrease in time spent in acute care and home treatment services (35). Other studies also reported a reduction in relapses and hospitalization rates, including a decrease in relapse rates at 12 months (Budiarto et al., 2019b; Gomis et al., 2017b; Tessier et al., 2023a). In the randomized clinical trial by Malakouti et al., home visits were associated with lower relapse and rehospitalization rates compared with telephone follow-up and outpatient care (Malakouti et al., 2016b).

In the study by Yasuma et al., rehospitalization rates at six months were reported among participants receiving brief family psychoeducational intervention and in the control group (Yasuma et al., 2024b). A descriptive study found no statistically significant association between pharmacological treatment and hospitalization reduction (Alston M et al., 2019b).

Regarding symptomatology, Basavaraju et al. documented a reduction in symptoms, including improvements in clinical severity among individuals with schizophrenia (Basavaraju V et al., 2022b). The study by Kumar et al. examined the effectiveness of cognitive rehabilitation: both home-based and clinical groups reported significant cognitive improvements measured through the NIMHANS Neuropsychological Battery (National Institute of Mental Health and Neurosciences Neuropsychological Battery), but no statistically significant differences were found in positive and negative symptoms evaluated with the SAPS (Scale for the Assessment of Positive Symptoms) and SANS (Scale for the Assessment of Negative Symptoms scales) (Kumar D et al., 2019b).

Improved awareness of the disorder, assessed using the Scale for the Assessment of Insight (SAI), was reported in a systematic review and a meta-analysis (Kim SH & Park S, 2023a; Lyles et al., 2023a). A retrospective study reported greater adherence to therapeutic-rehabilitative treatment, as shown by improved Life Skills Profile (LSP) questionnaire scores (Hode et al., 2024a). This improvement was also confirmed in literature reviews (Gomis et al., 2017b; Iswanti DI et al., 2024b). However, other studies did not find significant differences (Chuttoo et al., 2019a; Kidd SA et al., 2018b; Tessier et al., 2023a).

Regarding suicide attempts, Hode et al. reported a reduction one year after the educational intervention (Hode et al., 2024b).

The identified health outcomes included reduced disability, greater satisfaction with care, and improved quality of life (considering social inclusion, stigma reduction, employment status, income, and social functioning).

Educational interventions demonstrated effectiveness in reducing disability, as reported in pilot studies (Basavaraju V et al., 2022b); improved adaptive functioning was also reported after the intervention, as measured by the Multnomah Community Ability Scale (MCAS) (32). Similar findings were reported in the literature reviews by Gomis et al. and Lyles et al. (Gomis et al., 2017b; Lyles et al., 2023b)

Quality of life, assessed in multiple studies, showed mixed results. Some studies found no significant post-intervention differences in quality of life and well-being measures (Kidd SA et al., 2018b; Malakouti et al., 2016b). However, one study reported improvements in specific domains of quality of life, particularly among individuals over 48 years of age and women (Moreno-Alonso et al., 2023a). Similar improvements in quality of life and overall functioning were also reported in the literature reviews and meta-analyses by Kim et al. and Lyles et al. (Kim SH & Park S, 2023a; Lyles et al., 2023b).

Educational interventions significantly improved participants' social inclusion and social functioning (Gomis et al., 2017b; Iswanti DI et al., 2024b; Lyles et al., 2023b). Satisfaction with received care was higher in home-based settings, as reported by Malakouti et al. (Malakouti et al., 2016b). High levels of satisfaction with received care were also reported in the study by Moreno Alonso et al., based on participant surveys (Moreno-Alonso et al., 2023a). Similar findings were also reported in literature reviews and meta-analyses (Gomis et al., 2017b; Kim SH & Park S, 2023a; Lyles et al., 2023b).

RQ3: What are the expected health outcomes for the ICs?

Caregivers benefited in terms of health following the implementation of educational strategies, including acquiring knowledge, developing new skills and strategies, reducing

perceived burden, and improving quality of life.

Iswanti and Nursalam reported that the empowerment intervention improved caregivers' ability to prevent relapses compared with the control group. Caregivers in the intervention group also showed greater involvement in supporting medication adherence, meeting activities of daily living needs, enhancing productive skills, and facilitating patients' social interactions (Iswanti DI et al., 2024a).

Home-based and family educational interventions increased caregivers' knowledge about the disorder, although these improvements were not always maintained over time (Davtian & Scelles, 2014; Kidd SA et al., 2018a; Malakouti et al., 2016a; Widiyawati W et al., 2020). Psychoeducational interventions also effectively addressed feelings of exhaustion and personal invasion and reduced predisposing factors for burden, such as high emotional expressiveness and social stigma (Chen et al., 2019; Chuttoo et al., 2019b). However, the risk of burden was higher when caregivers were seen solely as "auxiliaries" in patient care, disregarding their own family needs (Davtian et al., 2017). Significant improvements were also reported in family burden, as measured by the BAS scale and the IEQ questionnaire, while a relatively low burden emerged among caregivers who had received community support interventions and among those caring for patients with mild conditions compared to severe disorders(Basavaraju V et al., 2022a; Kumar D et al., 2019a; O'Neill et al., 2022; Tessier et al., 2023b). Nevertheless, some findings were less consistent, as one observational study found no statistically significant differences in the CORE scale, and one clinical trial showed a decrease in burden over time in the intervention group without statistically significant differences between groups(Budiarto et al., 2019a).

Psychoeducation also reduced anxiety and improved psychological well-being, with reductions in ZBI and CES-D scores and an increase in caregivers' spiritual well-being (Davtian & Scelles, 2014; Ilmy et al., 2022; Lyles et al., 2023a). Improvements in quality of life and family relationships were also confirmed by systematic reviews and other studies (Chuttoo et al., 2019b; Davtian et al., 2017; Iswanti DI et al., 2023; Lavis A et al., 2015). However, not all studies reported significant differences, particularly with regard to quality of life, psychological well-being, or therapeutic alliance with professionals (Davtian & Scelles, 2014; Kidd SA et al., 2018a). Finally, family interventions were found to reduce burden and improve knowledge about the disorder, coping strategies, mental health, and overall well-being, although no significant differences emerged in family relationships or perceived social support (Peng MM et al., 2022).

RQ4: What are the main barriers and facilitators in the implementation of these interventions?

Training sessions promoted knowledge-sharing within a supportive setting, allowing families to express their needs (Davtian & Scelles, 2014). However, the complexity of family issues can hinder healthcare professionals from implementing therapeutic approaches (Iswanti DI et al., 2023). Caregivers faced difficulties in collaborating with mental health services when excluded from care plans, despite their ability to identify warning signs of deterioration (Mathew & Mathias, 2024; O'Neill et al., 2022). Additionally, the use of language evoking guilt or reinforcing stereotypes created further challenges (Davtian et al., 2017; Kidd SA et al., 2018a).

During exacerbations, home-based treatment appeared to be preferred because of its perceived benefits on quality of life compared with hospitalization (Lavis A et al., 2015). It also facilitated adherence among individuals with difficulties accessing hospital facilities, while weekly planning was supported by the structured tasks assigned by professionals (Mathew & Mathias, 2024).

Kidd et al., comparing cognitive training (CAT) with the Mueser and Gingerich Guide, highlighted caregivers' struggles in implementing interventions independently and emphasized the need for professional supervision, clear strategies, and support materials (Kidd SA et al., 2018a). Other studies also used educational tools such as guide manuals (Kidd SA et al., 2018a; Tessier et al., 2023b), informational brochures (Malakouti et al., 2016a), illustrations (Yasuma et al., 2024a), and DVDs (Kidd SA et al., 2018a).

Barriers to therapeutic adherence included a lack of understanding of follow-up importance, absence of a caregiver, loss of trust in the treatment process, social stigma, false beliefs, and financial difficulties (Basavaraju V et al., 2022a; Budiarto et al., 2019a; Chen et al., 2019; Lyles et al., 2023a; Mathew & Mathias, 2024). Alston et al.'s study found that family involvement improved adherence to pharmacological therapy

(p=0.0177) but did not increase compliance with rehabilitation treatments. Telemedicine was found to be less effective than in-person treatment, while living in rural areas did not affect dropout rates (Alston M et al., 2019a). However, families often sought guidance from shamans or religious leaders, sometimes resorting to violence or physical restraint(Ilmy et al., 2022; Mathew & Mathias, 2024).

Social stigma limited individuals' potential in achieving their goals (Widiyawati W et al., 2020) and led some to refuse medication, particularly if perceived as ineffective (Mathew & Mathias, 2024; Peng MM et al., 2022). To enhance understanding and family involvement, cultural adaptations were necessary, such as the use of idiomatic expressions and religious references (Lyles et al., 2023a).

RQ5: What are the implications for nursing practice?

Only a limited number of studies specifically addressed the role of nurses, who were primarily involved as part of multidisciplinary teams delivering interventions or mental health services (Budiarto et al., 2019a; Kumar D et al., 2019a; Tessier et al., 2023b; Yasuma et al., 2024a). Their contribution included strengthening relationships with caregivers and improving understanding of psychoeducational topics in multifamily groups (Davtian & Scelles, 2014). In CRHTs, nurses collaborated with psychiatrists, often acting as case managers to assess eligibility for home care and, in most cases, delivering the intervention independently (Basavaraju V et al., 2022a; Lavis A et al., 2015). Other studies also described autonomous nurse-led interventions, sometimes integrating nursing care and psychoeducation (Ilmy et al., 2022; Kidd SA et al., 2018a). Nurse case managers further supported individuals through home visits, and access to emergency telephone support contributed to positive outcomes (Widiyawati W et al., 2020). Foster Homes still presented difficulties related to professional relationships, daily management, and the integration between private and professional life (Gomis et al., 2017a; Tramier et al., 2021), while family-based programs emphasized both individual well-being and intrafamily dynamics (Davtian et al., 2017). Some families reported benefits of rehabilitation, whereas others highlighted the need for greater funding and support (Hode et al., 2024a; Kurtz & Mueser, 2008).

Mind Map of Results

Figure 3 presents a comprehensive conceptual map illustrating the relationship between home-based educational interventions for caregivers and the main domains identified in the literature. The map summarizes the different educational strategies, the associated barriers and facilitators, the expected outcomes for caregivers and individuals with psychosis, and the implications for clinical practice.

Discussion

Home-based and Foster Home educational interventions may help reduce exacerbations in individuals with psychosis (Gomis et al., 2017a; Kim SH & Park S, 2023b), highlighting a lower risk of hospitalization compared to patients followed on an outpatient basis or through telephone follow-up (Malakouti et al., 2016a). Psychoeducation may help reduce exacerbations in individuals with psychosis (Gomis et al., 2017a; Tessier et al., 2023b) and it remains, to date, one of the best interventions for reducing relapse rates and improving health outcomes. However, family psychoeducation appears to be a relevant educational strategy, although the evidence does not allow firm conclusions regarding its superiority over home-based psychoeducation (McFarlane, 2016).Combined approaches, such as social skills training associated with cognitive-behavioral therapy (CBT), Early Intervention Services (EIS), and Crisis Resolution Home Treatment teams (CRHTs), or psychoeducation integrated with psychosocial interventions, also reduce hospitalizations, acute service access, and length of stay as reported in other studies (Bird et al., 2013; Chuttoo et al., 2019b; Gomis et al., 2017a). However, some studies suggest that cognitive-behavioral therapy did not lead to benefits (Marshall & Rathbone, 2011). Psychoeducation combined with CBT may represent a promising strategy, with some evidence suggesting a reduction in suicide attempts. (Chuttoo et al., 2019b; Hode et al., 2024a) as reported in other studies (Jeong et al., 2023; Zhao et al., 2015). Family support is crucial in reducing exacerbations and improving treatment adherence (Iswanti DI et al., 2023;

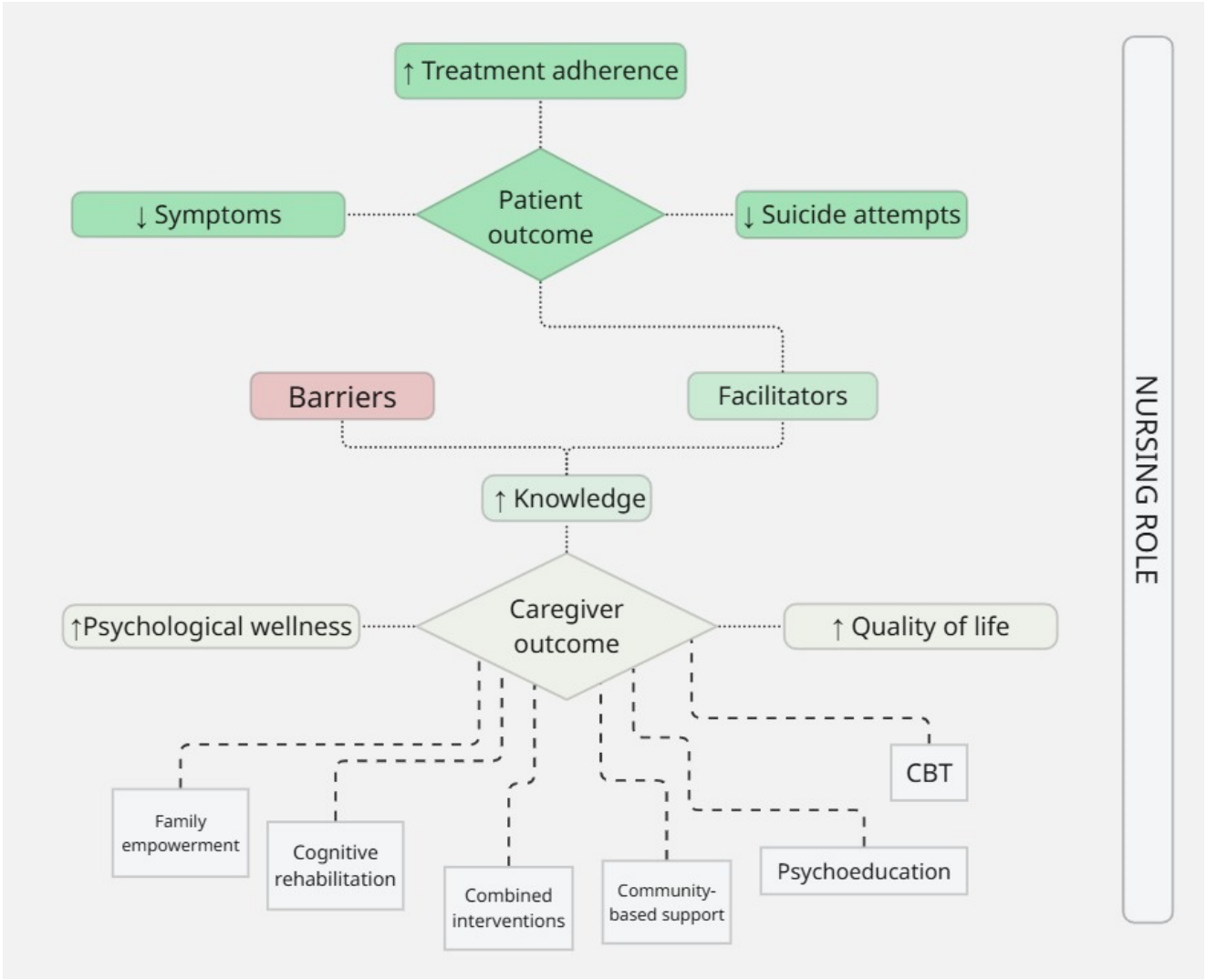


Figure 3. Mind map of caregiver-focused nursing strategies in individuals with psychosis.

Lyles et al., 2023a; Widiyawati W et al., 2020). In relation to this aspect, several interventions appeared to be associated with positive outcomes, including CRHTs, EHS social skills training, the community-based RISE intervention, and family empowerment interventions based on narrative therapy (Gomis et al., 2017a; Hode et al., 2024a; Iswanti DI et al., 2023). However, the outcomes associated with CRHTs may vary according to the patient's clinical profile (Sampogna et al., 2023). Moreover, EHS has shown beneficial effects, particularly on social functioning and negative symptoms in psychosis, although the evidence is not equally strong across all outcomes (Turner et al., 2018). The RISE protocol appears to be a promising intervention, although further studies are needed before drawing firm conclusions about its effectiveness (Asher et al., 2022). Combined interventions, including psychoeducation with social skills training or nursing care, CBT, community-based interventions, and family empowerment with self-learning, may contribute to reducing positive symptoms (Gomis et al., 2017a; Iswanti DI et al., 2023; Lyles et al., 2023a; Malakouti et al., 2016a). Among these, cognitive rehabilitation also reduces cognitive symptoms (Gomis et al., 2017a; Kumar D et al., 2019a), and family interventions and CBT also improve illness awareness (Kim SH & Park S, 2023b; Lyles et al., 2023a).

The included studies suggest that individuals with psychosis may experience difficulties in daily activities, social relationships, and occupational functioning (Alston M et al., 2019a; Barranha et al., 2021). Several interventions were associated with reductions in disability, including community-based interventions, psychoeducation, cognitive rehabilitation, and self-learning., and programs in Foster Homes (Basavaraju V et al., 2022a; Gomis et al., 2017a; Iswanti DI et al., 2023; Kidd SA et al., 2018a; Lyles

et al., 2023a). Social skills training EHS and home care also improve social functioning (Gomis et al., 2017a; Lyles et al., 2023a) according by international literature (Kurtz & Mueser, 2008; Turner et al., 2018) Interventions like ODA, CRHTs, and psychoeducation improve quality of life from an emotional, physical, and social standpoint (Gomis et al., 2017a; Kim SH & Park S, 2023b; Lyles et al., 2023a; Moreno-Alonso et al., 2023b), and the latter increases care satisfaction (Gomis et al., 2017a; Lyles et al., 2023a; Moreno-Alonso et al., 2023b).

Single or combined psychoeducation with nursing care, family empowerment, and narrative therapy improves caregiver skills (Iswanti DI et al., 2023, 2024a; Kim SH & Park S, 2023b; Malakouti et al., 2016a; Tessier et al., 2023b; Yasuma et al., 2024a), who show gaps in knowledge about the illness, crisis management, and follow-up (Ilmy et al., 2022; O'Neill et al., 2022; Oyelade OO & Nkosi-Mafutha NG, 2022; Tramier et al., 2021). However, after acquiring knowledge, the caregiver might become excessively vigilant about symptoms of exacerbation (Lavis A et al., 2015) as already confirmed by other authors (Frias et al., 2020; Sefasi et al., 2008). Other risk factors for burden include the severity of patient symptoms, financial sacrifices, changes in family relationships, stigma, and social isolation (Cechnicki A et al., 2023; Chen et al., 2019; Ilmy et al., 2022; Mathew & Mathias, 2024; O'Neill et al., 2022; Oyelade OO & Nkosi-Mafutha NG, 2022; Peng MM et al., 2022). Cognitive adaptation training (CAT), community-based interventions, self-learning programs, and yoga reduce burden, but family psychoeducation also reduces predispositional risk factors (social stigma, stress, emotional expression) and the risk of mental disorders in the caregiver (Basavaraju V et al., 2022a; Cechnicki A et al., 2023; Iswanti DI et al., 2023; Kidd SA et al., 2018a; Kim SH & Park S, 2023b; Lyles et al., 2023a; Tessier et al., 2023b). Furthermore, the combined intervention of nursing care with psychoeducation also improves caregiver self-esteem and encourages feelings of hope and motivation (Budiarto et al., 2019a).

According to the findings of this review, family caregivers play a central role in the treatment of people with psychosis and schizophrenia and should be considered partners in care, not merely informal supporters. This is consistent with clinical guidelines and systematic reviews that identify family involvement and family interventions as evidence-based aspects of mental health care (Eassom et al., 2014; NICE, 2015). For people with psychosis and schizophrenia, educational support for family caregivers should start at an early stage, be maintained over time, and be responsive to the particular needs of each family. This approach is supported by clinical guidelines and by recent evidence highlighting the importance of nurse-led, individualized psychoeducational interventions (Kuipers et al., 2025; NICE, 2015). Home-based psychiatric nursing and nurse case management appear to play a key role in the care of people with psychosis and schizophrenia, as they support continuity of care, symptom monitoring, family education, crisis support, and community-based management (Malakouti et al., 2016a). Although multidisciplinary care remains the preferred model in psychosis and schizophrenia, evidence suggests that nurses can also act autonomously in specific areas, including family psychoeducation, home-based follow-up, symptom monitoring, and case management (Malakouti et al., 2016a; NICE, 2015).

However, follow-up is hindered by a lack of coping strategies among caregivers, poor awareness of the importance of monitoring (Basavaraju V et al., 2022a; Hode et al., 2024a), and difficulties in accessing technology in rural areas (Alston M et al., 2019a; Kidd SA et al., 2018a). Telemedicine, although useful in overcoming distances, appears less effective than in-person visits, possibly due to reduced engagement with professionals (Alston M et al., 2019a). Educational interventions were frequently delivered by multidisciplinary teams in the included studies. Therefore, only selected examples of these teams are described to illustrate their role in the interventions (Chuttoo et al., 2019b; Gomis et al., 2017a; Lavis A et al., 2015; Moreno-Alonso et al., 2023b; Tessier et al., 2023b), rather than by a single operator (Budiarto et al., 2019a; Malakouti et al., 2016a; Yasuma et al., 2024a), due to the contribution of various competencies that ensure a comprehensive and integrated perspective in the therapeutic-rehabilitative plan and the possibility of offering the service to a larger number of users while ensuring quality. Additionally, seeking collaboration with local organizations can increase the outreach impact (Cechnicki A et al., 2023; Lyles et al., 2023a).

Further studies could investigate whether

specific nursing interventions may be effective in improving caregivers' quality of life and examine the durability of the benefits associated with the interventions identified.

This scoping review provides a broad overview of the available evidence and helps identify key gaps in the literature. A strength of this review is the inclusion of heterogeneous study designs, interventions, and outcomes, which allowed a wide exploration of the available evidence on educational interventions, clinical and health outcomes, and the role of nurses and multidisciplinary teams.

However, some limitations should be acknowledged. No critical appraisal was conducted to assess the methodological quality of the included studies. In addition, grey literature was not included, which may have limited the comprehensiveness of the review. Finally, no protocol was registered or published, which may have reduced the transparency and reproducibility of the review process.

Conclusions

This scoping review highlights that home-based strategies for informal caregivers of patients with psychosis may improve health outcomes for both caregivers and patients. Research studies have been conducted in different countries with diverse sociocultural and economic contexts, limiting the possibilities for comparing the applicability of educational strategies.

At present, psychoeducation appears to be a promising intervention for achieving this goal. Moreover, psychoeducation combined with other approaches, including nursing care, appears to improve symptom management, treatment adherence, and quality of life in patients with psychosis, while also enhancing caregivers' skills and abilities.

Nursing plays an important role through therapeutic education, monitoring, and case management, and is essential in supporting both patients and their family members. This review also identified important barriers to implementation, including stigma, financial burden, limited access to services, insufficient support from professionals, and the need for individualized interventions.

Given the heterogeneity of the available evidence, these findings should be interpreted with caution. Finally, home-based interventions represent a relevant and promising area for mental health care.

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Review

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Urinary Incontinence Management Using Sensor-Based Technologies: A Systematic Review with Narrative Synthesis

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Abstract

Background. Urinary incontinence (UI) is prevalent in older populations. UI is associated with reduced quality of life, skin complications, and increased caregiver burden. Sensor-based UI technologies have been introduced to support timely and individualized care beyond routine check-and-change practices, but their effectiveness remains unclear.
Objectives: To examine the sensor-based technologies used in UI care and to synthesize evidence regarding their effects on patient and caregiver outcomes.
Methods. A search was conducted in December 2025 using five databases (PubMed, CINAHL, EMBASE, the Cochrane Library, and IEEE Xplore) in accordance with the PRISMA guidelines. Search terms included "urinary incontinence," "smart diaper," "smart pad," "sensor," "wearable sensor," and "continence monitoring," combined using Boolean operators (AND, OR) and controlled vocabulary (e.g., MeSH, EMTREE). Studies included if they applied sensor-based UI technologies embedded in pads or diapers, and reported clinical outcomes related to UI care.
Results. Eight studies were included. Sensor-based UI technologies ranged from systems that detected voiding, leakage, saturation, or urine volume and provided alerts to advanced systems using sensor-derived data for voiding pattern analysis and individualized care planning. Technical performance and care-process outcomes were mixed, although some studies reported improvements in pad checking, leakage,

body had no role in the design of the study.

absorbent product use, and adherence to individualized care plans. Patient outcomes showed limited improvements, with some benefits in skin condition, continence-related outcomes, and sleep interruptions. Caregiver outcomes generally indicated favorable usability, perceived usefulness, and support for decision-making, although controlled studies did not demonstrate improvements in caregiver burden, work engagement, or organizational headroom. Evidence regarding informal caregivers remained limited.

Conclusion. Sensor-based UI technologies may support more timely and individualized UI care by improving care processes and caregiver decision-making. Given the important role of informal caregivers in UI care, future research should evaluate the effects on informal caregiver outcomes.

Keywords: Urinary Incontinence, Sensors, Adult Diapers, Wearable Electronic Devices, Nursing Care, Systematic Review

Introduction

Urinary incontinence (UI) is defined as any involuntary leakage of urine (Haylen et al., 2010) and represents a significant global public health concern (Gröning et al., 2024). The prevalence of UI is estimated to be approximately 25–45% among adults worldwide, with substantially higher rates reported among women and older populations (Bishop et al., 2025; Patel et al., 2022). Given the rapid growth of the aging population, the burden associated with UI is expected to increase substantially in the coming decades (Milsom & Gyhagen, 2019; Patel et al., 2022).

Beyond bladder dysfunction, UI exerts negative consequences across multiple dimensions of individual health. UI has been associated with urinary tract infections, sleep disturbances, falls, and skin damage caused by exposure to moisture (Gröning et al., 2024; Soysal et al., 2023). Inadequate management of UI increases the risk of incontinence-associated dermatitis (IAD), pressure injuries, secondary infections, and sepsis (Kottner & Dissemond, 2025). In addition to these physical consequences, UI can negatively affect psychological and social well-being, contributing to reduced quality of life, depression, anxiety, social isolation, and stigma (Pizzol et al., 2021; Soysal et al., 2023).

Effective UI care requires individualized continence management based on each person's voiding patterns, care needs, and functional abilities (Department of Veterans' Affairs, 2020; van Cooten et al., 2025). Its implementation, however, is often limited in hospitals and long-term care settings by staffing shortages, workload demands, rigid routines, and insufficient organizational support (Marcu et al., 2024; Skotnes et al., 2013). UI care often relies on routine check-and-change practices using absorbent products, which are performed according to predetermined schedules rather than individual voiding patterns (Wagg et al., 2025). Repeated manual checks of absorbent products may compromise privacy and dignity (Department of Veterans' Affairs, 2020). Premature pad replacement can result in unnecessary product waste, whereas delayed replacement may increase the risk of leakage, skin damage, and IAD (Rajabali et al., 2023; Wagg et al., 2025). These challenges may be particularly pronounced among individuals with cognitive impairment who are unable to communicate their toileting needs effectively.

To address these challenges, various digital technologies have recently been introduced into UI care. Examples include smartphone applications, telemonitoring systems, wearable devices, and sensor-based absorbent products (Weinstein et al., 2022; Zhu et al., 2025). Among these, sensor-based UI technologies have received particular attention for their potential to enable real-time detection of voiding events or pad saturation, thereby supporting timely and individualized UI care (Cho et al., 2021; Rajabali et al., 2023). Such technologies have been reported to reduce unnecessary pad checks and changes, lower the risk of complications such as

IAD, and preserve residents' sleep quality and dignity (Rajabali et al., 2023; Wagg et al., 2025).

Despite this growing interest, the existing evidence base remains fragmented. Prior reviews have examined broad digital and technological approaches to UI management, including telemonitoring, app-based interventions, and ultrasound (Gröning et al., 2024; Omotunde & Wagg, 2023). Other reviews have focused on non-invasive bladder urine volume estimation using electrical impedance-based methods (Noyori et al., 2022) or sensor-based products without synthesizing clinical outcomes (Jeong & Park, 2019). Evidence regarding their clinical effectiveness across patient and caregiver outcomes remains limited and has not been systematically synthesized.

This systematic review aimed to examine the characteristics of sensor-based technologies used in UI care and to synthesize evidence regarding their effects on patient and caregiver outcomes. This review provides evidence on the current utilization and effectiveness of these technologies and informs their future application.

Methods

This study was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page et al., 2021). The key terms and research question were structured according to the population, intervention, comparison, outcomes, and study design (PICOs) framework as follows: (1) population: people with UI or people requiring UI care; (2) intervention: sensor-based UI technologies embedded in or attached to absorbent products or wearable continence devices to detect voiding-related events; (3) comparison: standard care, alternative intervention, or no intervention; (4) outcomes: all outcomes related to UI management; and (5) study design: randomized controlled trials, non-equivalent control group experimental designs, and single-group pre-post studies (pre-experimental designs). This review was registered in the PROSPERO database (registration number: CRD420261384275).

Search strategy

A literature search was conducted in PubMed, CINAHL, EMBASE, the Cochrane Library, and IEEE Xplore databases without restrictions on the publication period. The final search was conducted on December 14, 2025. Search terms included "urinary incontinence," "smart diaper," "smart pad," "sensor," "wearable sensor," and "continence monitoring," combined using Boolean operators (AND, OR) and controlled vocabulary (e.g., MeSH, EMTREE). The search strategies were reviewed by an academic librarian. The complete search strategies for each database are provided in Supplementary Material A.

Eligibility criteria

Studies were included in this review if they met the following criteria: (1) studies conducted with people with UI or people requiring UI care; (2) studies using sensor-based technologies as an intervention for continence management; (3) studies employing intervention-based research designs; (4) studies published in English.

Studies were excluded if they met the following criteria: (1) studies not involving people with UI or people requiring UI care; (2) studies not incorporating sensor-based technology; (3) non-intervention studies, such as reviews, qualitative studies, or technology development studies; (4) grey literature, including dissertations and research reports; (5) studies without accessible full texts; and (6) studies published in languages other than English.

Study selection and data extraction

All retrieved records were managed using EndNote 21 reference management software. After duplicate records were removed, two independent reviewers (DL and KK) screened the titles and abstracts of the identified studies. Studies that appeared potentially eligible were then subjected to full-text review to confirm final inclusion. Any disagreements arising during the screening process were resolved through discussion among the reviewers (JL, DL, and KK) during research meetings.

Three reviewers discussed and established the data extraction items during a research meeting prior to the review process. The extracted data included the author, publication year, country, study design, setting/sample, age, technology

type, intervention, and duration/evaluation (Table 1), as well as study outcomes (Table 2). Two reviewers (DL and KK) independently extracted the data, and the extracted information was subsequently verified against the full texts by another reviewer (JL).

Data synthesis

Substantial heterogeneity was observed across intervention characteristics and outcome measures. The findings were synthesized using a narrative approach without meta-analysis. The classification framework was developed after data extraction based on the review aim and the extracted data. The characteristics of sensor-based UI technologies and the outcomes associated with their use were synthesized separately. The functional characteristics of the technologies were classified into three components: sensing functions, notification systems, and pattern monitoring with individualized UI care planning. Outcomes were classified into three domains: technical performance, patient outcomes, and caregiver outcomes. Technical performance included detection and measurement performance as well as operational measures related to continence care. Patient outcomes included clinical, functional, psychosocial, and quality-of-life outcomes. Caregiver outcomes included device usability, perceived usefulness, and adherence among caregivers or healthcare workers who used the devices. The findings were tabulated and narratively compared within each category. Outcomes were retained in their originally reported formats.

Quality appraisal

Two independent reviewers (DL and KK) conducted quality assessments of the included studies. For randomized controlled trials, the Joanna Briggs Institute (JBI) Checklist for Randomized Controlled Trials was utilized (Barker et al., 2023), while the JBI Checklist for Quasi-Experimental Studies was applied to non-randomized experimental studies (Barker et al., 2024). Discrepancies between the reviewers were resolved through consensus discussions during research meetings (JL, DL, and KK).

Results

The study selection process is presented in Figure 1. The database search yielded 3,930 records. After removing 2,133 duplicates, 1,797 records were screened by title and abstract, of which 1,744 were excluded. Of the 53 full-text articles assessed for eligibility, 45 were excluded because they did not meet the inclusion criteria. Specifically, 28 studies evaluated non–sensor-based interventions, 12 focused solely on device development, three did not include clinical evaluation, one was classified as gray literature, and one was published in a language other than English. Finally, eight studies met the inclusion criteria and were included in the final synthesis.

The methodological quality of all included studies was assessed using the JBI Critical Appraisal Tools. Three studies employing a randomized controlled trial design were evaluated using the JBI Checklist for Randomized Controlled Trials (Barker et al., 2023). The remaining five studies were evaluated using the JBI Checklist for Quasi-Experimental Studies (Barker et al., 2024). In accordance with the revised JBI Critical Appraisal Tools, item-level judgments were reported descriptively, and studies were not excluded based on a total appraisal score. Although several studies had methodological limitations, all studies were retained for synthesis after discussion and consensus among the reviewers. Detailed results of the critical appraisal are presented in Supplementary material B.

Characteristics of the included studies

The characteristics of the included studies are presented in Table 1. A total of eight studies published between 2004 and 2025 were included in this review. The studies were conducted in Australia (n = 2), Canada (n = 2), Poland (n = 1), Korea (n = 1), United Kingdom (n = 1), and the Netherlands (n = 1), with one study conducted across Canada and Germany. The included studies comprised three randomized controlled trials, two quasi-experimental studies, and three single-group intervention studies. Across all studies, a total of 539 participants were included, with sample sizes ranging from 30 to 156 participants. Four studies were conducted in nursing homes or residential care facilities, two in acute care hospitals, one in a home

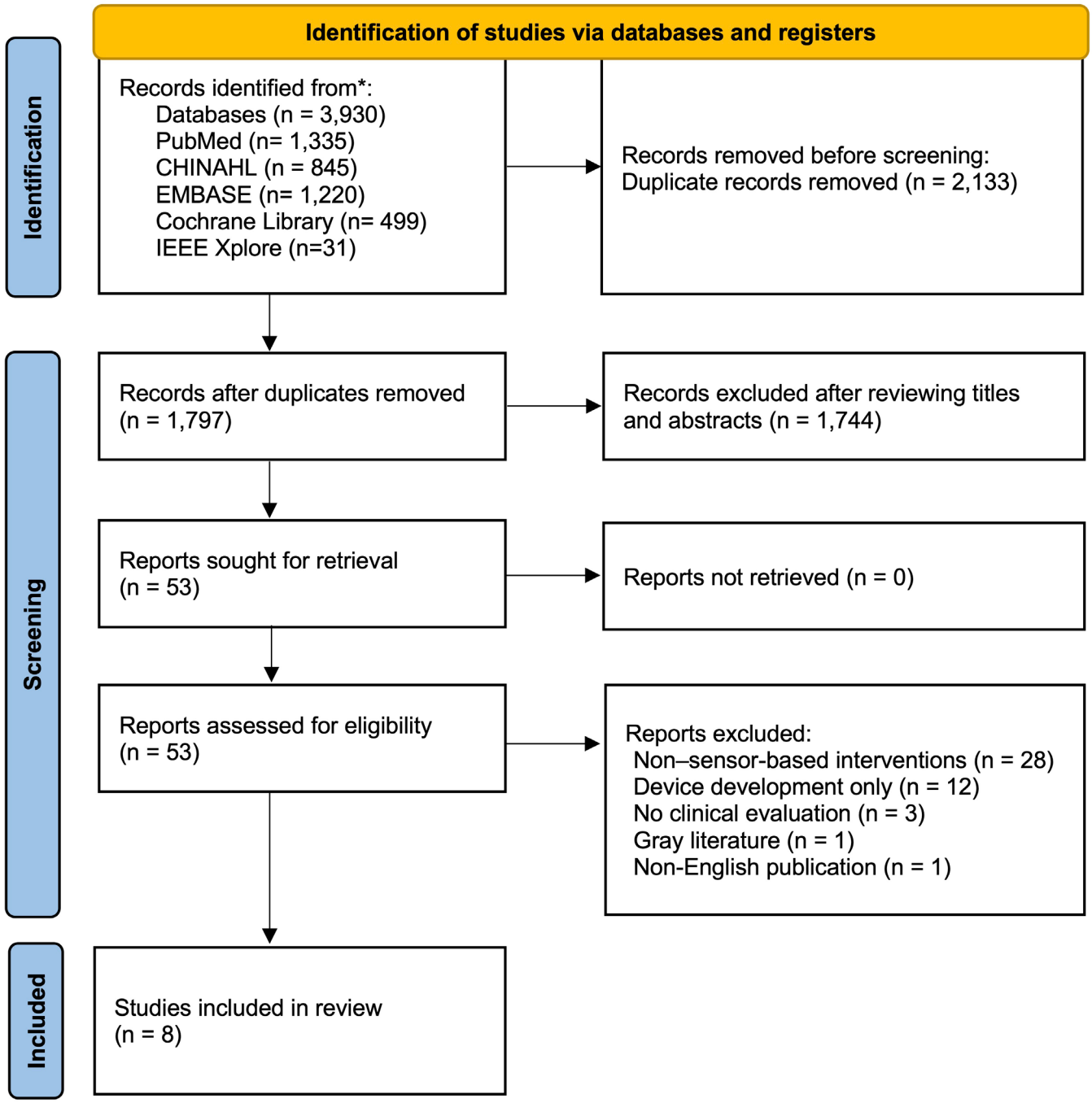


Figure 1. PRISMA Flowchart of the study

care setting, and one across community-based settings. Most participants were people with UI, and two studies included people with UI who were unable to communicate their UI care needs (van Cooten et al., 2025; Wagg et al., 2025). The mean or median age of participants ranged from 45.4 to 88.5 years, and the proportion of female participants ranged from 43.0% to 100%.

Characteristics of sensor-based UI technologies

The sensor-based UI technologies were categorized into three key functional components: sensing functions, notification systems, and pattern monitoring with individualized UI care planning.

Sensing functions

Sensing functions varied across technologies, including voiding detection, urine volume estimation, saturation sensing, and leakage detection. Voiding detection identifies the occurrence of a urination event. Nikoletti et al.

care setting, and one across community-based settings. Most participants were people with UI, and two studies included people with UI who were unable to communicate their UI care needs (van Cooten et al., 2025; Wagg et al., 2025). The mean or median age of participants ranged from 45.4 to 88.5 years, and the proportion of female participants ranged from 43.0% to 100%.

Notification systems

Six of the eight included studies incorporated caregiver notification functionalities. The predominant delivery method involved smartphone- or mobile device–based applications, through which sensor-derived wetness or saturation data were transmitted via Bluetooth or wireless communication systems to support timely UI care. Long et al. (2015) used wearable smart underwear that provided lower-abdominal vibration alerts when urine reached the embedded sensor threads.

Pattern monitoring and individualized UI care planning

Four studies incorporated pattern-monitoring functions that utilized continence data to identify individual voiding patterns and inform individualized UI care planning. Three studies relied on manual interpretation of sensor-collected data by healthcare professionals to develop individualized toileting schedules and care plans (Nikoletti et al., 2004; van Cooten et al., 2025; Yu et al., 2014). In contrast, Rajabali et al. (2023) employed an automated pattern-analysis system that compiled voiding data transmitted to a secure remote server and generated structured continence assessment reports to support individualized care planning.

Outcome

Outcomes associated with device use were grouped into three domains: technical performance, patient outcomes, and caregiver outcomes. Detailed findings are presented in Table 2.

Technical performance

Technical performance outcomes were classified as direct device performance and derived outcomes. Direct outcomes included detection accuracy and false alarms, while derived outcomes included pad checking behavior, product use, care time, and costs. Direct device performance was evaluated in two studies. Cho et al. (2021) compared sensor-estimated urine volume with manually measured urine volume and reported high agreement between the two measures, while Long et al. (2015) reported pad leakage alerts in 86% of leakage events and timely alerts in 82% of events. Outcomes derived from technology use were reported in four studies. Rajabali et al. (2023) reported significant reductions in night pad absorbency and total 24-hour pad absorbency, although no significant differences were observed for day pad absorbency or the number of pads used. Similarly, Wagg et al. (2025) found a significant reduction in daily total pad absorbency. Pad-checking behavior was assessed in three studies. Agholme et al. (2023) reported a reduction in daily pad checks, whereas the other two studies found no significant between-group differences in wet checks or pad checks (Rajabali et al., 2023; Wagg et al., 2025). Leakage frequency was assessed in three studies and showed inconsistent findings. Significant reductions in leakage episodes were reported in two studies (Agholme et al., 2023; Rajabali et al., 2023), whereas van Cooten et al. (2025) reported greater reductions in the waiting-list group than in the intervention group. In contrast, findings related to pad change frequency were mixed, with only one study reporting a reduction in incontinence material changes (van Cooten et al., 2025), while others found no significant differences (Agholme et al., 2023; Wagg et al., 2025). Time spent on UI care was assessed in three studies, none of which reported a significant reduction following the intervention (Rajabali et al., 2023; van Cooten et al., 2025; Wagg et al., 2025). Wagg et al. (2025) further reported no significant between-group differences in toilet visits, clothing changes, linen changes, or the time between pad saturation notification and pad change. Agholme et al. (2023) reported no device-related adverse events, and no significant changes were observed in fecal incidences.

Patient outcomes

All studies reported patient outcomes. Skin-related outcomes were assessed in three studies. Two studies reported improvements in skin conditions, including resolution of skin redness or irritation and improvement of existing IAD or pressure injuries (Agholme et al., 2023; Cho et al., 2021). In contrast, Wagg et al. (2025) found no significant between-group differences in skin health outcomes, although non-inferiority of the intervention was demonstrated. Continence-related outcomes were assessed in three studies. Long et al. (2015) reported no change in UI symptom severity, while Nikoletti et al. (2004) reported only a within-group improvement in UI severity. In contrast, Yu et al. (2014) demonstrated significant improvements in several continence-related outcomes. Quality of life and well-being outcomes were assessed in four studies. No significant between-group improvements were observed in quality of life or well-being outcome (Rajabali et al., 2023; van Cooten et al., 2025; Wagg et al., 2025), although Rajabali et al. (2023) reported significant within-group improvements. Long et al. (2015) also found no significant overall improvement in lower urinary tract symptom-related quality of life, except for a significant improvement in the travel restriction item. Long et al. (2015) also assessed the psychosocial impact of the device after use and reported positive scores across competence, adaptability, and self-esteem domains. Sleep-related outcomes were assessed in one study, which demonstrated a significant reduction in daily sleep interruptions following the intervention, whereas no significant differences were observed in responsive behavior scores (Wagg et al., 2025). Cognitive impairment and ADL outcomes were evaluated in one and two studies, respectively, with no significant improvements reported (Nikoletti et al., 2004; Rajabali et al., 2023).

Caregiver outcomes

Seven studies reported caregiver outcomes. Only one study reported outcomes related to informal caregivers (Cho et al., 2021). Descriptive caregiver experience findings were generally favorable. Agholme et al. (2023) reported high usability and perceived usefulness, whereas Cho et al. (2021) found that 59% of caregivers were willing to purchase the system despite implementation difficulties reported by 41% of caregivers. Adherence-related outcomes were reported in three studies, with generally favorable adherence to individualized UI care plans (Nikoletti et al., 2004; Rajabali et al., 2023; Yu et al., 2014). In contrast, controlled studies found no clear effects on caregivers' physical burden, work engagement, or organizational headroom (van Cooten et al., 2025; Wagg et al., 2025). Qualitative findings from two studies identified both perceived benefits and implementation barriers, including improved resource utilization and quality of UI care, as well as device malfunction, lack of time, resistance to practice change, and limited organizational support (Nikoletti et al., 2004; Rajabali et al., 2023).

Discussion

This systematic review synthesized evidence on sensor-based technologies for UI management across technical performance, patient outcomes, and caregiver outcomes. The evidence suggests that these technologies have the potential to support continence care and caregiver decision-making.

This review identified changes over time in the functional use of sensor-based UI technologies. In earlier studies, sensor-derived voiding patterns were used to develop individualized toileting plans (Yu et al., 2014), whereas more recent systems incorporated real-time notification functions or automated pattern analysis to support caregiver decision-making (Cho et al., 2021; Rajabali et al., 2023). This finding is consistent with previous literature indicating that sensor-based UI care products are evolving beyond moisture detection to support care timing, continence assessment, and care delivery (Jeong & Park, 2019; Omotunde & Wagg, 2023). Real-time urine detection and change notifications are intended to support more timely UI care than fixed schedule-based care. Nevertheless, controlled evidence demonstrating improved response timing remains limited. For example, Wagg et al. (2025) found no significant between-group difference in the time between pad saturation notification and pad change. These notification-based systems remain reactive because they prompt a response after wetness, leakage, or saturation. Pattern monitoring combined with individualized

Table 1. Characteristics of studies included.

1st Author, year	Country	Study Design	Setting /Sample N (E/C)	Age / Sex (M%/F%)	Technology Type	Intervention (E / C)	Duration/ Evaluation
Agholme, 2023	Poland	Single-arm clinical trial	Home environment; older adults with UI receiving home care; N=35	74.0y (M:20.0%, F:80.0%)	Saturation sensing + notification	E: TENA SmartCare Change Indicator (reusable sensor on outside of pad + transmitter + smartphone app)E: TENA SmartCare Change Indicator (reusable sensor on outside of pad + transmitter + smartphone app)	3 weeks; T0: baseline, T1: learning week, T2: investigational week using device
Cho, 2021	Korea	Prospective single-arm pilot study	Acute care hospital; patients aged ≥50 years wearing diapers due to UI; N=30	80.8y (M:30.0%, F:70.0%)	Voiding detection + volume estimation system + notification	E: Smart diaper system (conductor-embedded diaper + sensing device + smartphone app); *Reference measurement: wet diaper weight recorded on FVCs	3–5 days; T0: baseline, T1: End of monitoring
Long, 2015	United Kingdom	Prototype product evaluation study	Outpatient clinics, general practice surgeries, community continence services, charities, and networks; women aged ≥18 years regularly using continence pads and experiencing pad leakage; N=55	67 y (M:0%, F:100%)	Pad leakage detection + notification	E: TACT3 Smart UnderWear (washable fixation pants + sewn-in conductive threads + removable signaling unit) *Reference measurement: leakage event diary during the first 7 days	2 weeks; T0: baseline, T1: week 2
Nikoletti, 2004	Australia	RCT with qualitative component	Acute care rehabilitation wards; elderly incontinent patients aged ≥65 years; N= 41(22/19) (only 6 completed CMC)	E: 82 y (M: 59%, F: 41%); C: 85 y (M: 37%, F: 63%)	Voiding detection + notification + pattern monitoring + individualized toileting plan	E: Habit training with electronic monitoring (sensor in pad, portable monitoring device) → individualized toileting plan C: Standard habit training → individualized toileting plan	72hr monitoring; T0: baseline, T1: 1 month after
Rajabali, 2023	Canada	Quasi-experimental mixed-methods study	Nursing home; residents aged >65 years requiring UI care; N= 89(43/46)	E=85.6y (M:18.6%, F: 81.4%); C= 88.5y (M:32.6%, F:67.4%)	Voiding detection + volume estimation system + automated pattern monitoring + individualized toileting plan	E: TENA Identifi (sensor-woven pads + transmitter logger + remote secure server) → Individualized toileting plan C: Usual care ("ask, check, and change")	72-h assessment; T0: baseline, T1: week 8, T2: week 16
van Cooten, 2025	Netherlands	Cluster RCT	Residential care facilities; people with PIMD and unable to communicate IM change need; N=156 (82/74)	E: 51.7 y (M 57%, F 43%); C: 45.4 y (M 53%, F 47%)	Saturation sensing + notification + pattern monitoring + individualized toileting plan	E: Abena Nova (urine sensors pad+ reusable clip + receivers + mobile app/online platform) C: Regular care	12 weeks; T0: baseline, T1: weeks 6, T2: week 12
Wagg, 2025	Canada, Germany	Cluster RCT	NH residents ≥65 y with UI, unable to consistently communicate toileting needs; check-and-change regimen; N= 102 (53/49)	E: Median age 87; C: Median age 87 y; Overall male 21.5% (detailed M/F by group not reported)	Saturation sensing + notification	E: TENA SmartCare Change Indicator (reusable sensor on outside of pad + transmitter + smartphone app) C: Usual check-and-change regimen	6 weeks; T0: baseline, T1: week 2, T2: week 6
Yu, 2014	Australia	Quasi-experimental study	NH; older residents with UI; N=31	81 y (F 78%)	Voiding detection + volume estimation system + pattern monitoring + individualized toileting plan	E: SIM telemonitoring system (sensor in pad + smartphone app + desktop computer)	12 weeks; T0: baseline, T1: week 2

Note. E = experimental group; C = control group; M = male; F = female; y = years; UI = urinary incontinence; NH = nursing home; PIMD = profound intellectual and multiple disabilities; IM = incontinence material; RCT = randomized controlled trial; FVC = frequency volume chart; CMC = continence monitoring chart; T0 = baseline; T1 = first follow-up; T2 = second follow-up

Table 2. Outcomes of Included Studies (Part 1).

1st Author, year	Technology Type	Outcomes	
Agholme, 2023	Saturation sensing + notification	Technical performance	▲ Checks per day (4.3→3.5, −16%, p=.001) ▲ Leakages per day (0.33→0.20, −40%, p=.005) △ Changes the absorbing products (3.3→3.0, NS) △ Fecal incidences per day (0.066→0.059, NS) – Safety: no serious device-related adverse events reported
		Patient outcome	- Skin redness / irritation: all 5 cases resolved by end of trial
		Caregiver outcome	- Usability: 83% rated device "very easy"; 89% overall usefulness "good"/"very good"; 89% would recommend – Caregiver perception: 71% reported reduced concern regarding patient comfort; 86% reported facilitated decision-making for diaper changes
Cho, 2021	Voiding detection + volume estimation system + notification	Technical performance	- Voiding detection rate: 32.8%; lower than expected - Urine volume measurement accuracy: mean difference −4.2 mL; 95% limits of agreement −96.7 to 88.3 mL; R^2=0.88 (p<.001)
		Patient outcome	- IAD and bed sore: no new occurrence; 1 case improved
		Caregiver outcome	- Caregiver experience: 59% willing to purchase; 41% reported system difficulties
Long, 2015	Pad leakage detection + notification	Technical performance	- Proportion of occasions alerted to pad leakage: 86% (95% CI: 79%–94%) - Proportion of occasions unaware of leakage prior to alert: 59% - Proportion alerted in time to change before leakage onto clothing/furnishings: 82% (95% CI: 76%–88%) - False alarms per day: mean 1.73 (95% CI: 0.79–2.66), median 0.5
		Patient outcome	△ ICIQ-UI Short Form: no change (prescore 15.0; postscore 15.0) △ ICIQ-LUTSqol: no significant change overall ▲ Effect on ability to travel: significant improvement (p<.05) - PIADS competence/ adaptability/ self-esteem: +0.44/ +1.1/ +0.93 - Overall impression: 92% good/OK (63% good, 29% OK) - Confidence levels: 92% would/might feel more confident (62% would, 30% might) - Willingness to purchase: 46% yes, 31% maybe - Comfort: >80% comfortable - Ease of washing: 93% easy to wash - Instructions for use: 98% good/OK - Design issues: press stud mechanism, bulky signaling unit, visibility under tight-fitting clothes, false alarms possibly triggered by perspiration
		Caregiver outcome	N/R
Nikoletti, 2004	Voiding detection + notification + pattern monitoring + individualized toileting plan	Technical performance	N/R
		Patient outcome	□ Cognitive impairment: at T0 (p=0.91), T1 (p=.82); △ both within-groups □ ADL: at T0 (p=.32), T1 (p=.81); △ both within-groups □ Frequency of incontinence: at T0 (p=0.96), T1 (p=.74); △ both within-groups □ Severity of incontinence: at T0 (p=.075), T1 (p=.686); △ in C, ▲in E↓ (p=.025) - Continence outcome by CMC (n=6): both groups improved; statistical analysis not conducted
		Caregiver outcome	- Compliance: case-study data only (C: 14–55%, E: 39–59%) - Nurses' perceptions (qualitative): device malfunction, lack of time, resistance to practice change, and inadequate support identified as key barriers
Rajabali, 2023	Voiding detection + volume estimation system + automated pattern monitoring + individualized toileting plan	Technical performance	■ Reduction in 24-h pad absorbency (50.6% vs 39.1%, p=.034) □ Number of day pads used ↓(p=.263); △ both within-groups □ Number of night pads used ↓(p=.499); △ both within-groups □ Absorbency of day pads used ↓ (p=.779); △ both within-groups ■ Absorbency of night pads used ↑ (p=.0001); △ in C, ▲in E↓ (p=.010) ■ Total absorbency of pads used in 24 h ↓ (p=.011); △ in C, ▲ in E↓ (p=.013) □ Total cost of day pads↓ (p=.275); △ both within-groups ■ Total cost of night pads ↓ (p=.048); △ in C, ▲ in E ↓ (p=.009) □ Number of pad leakages/24 h ↓ (p=.057); △ in C, ▲ in E ↓ (p=.016) □ Number of wet checks↓ (p=.193); △ both within-groups □ Reported time spent in continence care↓(p=.055); △ both within-groups
		Patient outcome	□ ADL↑ (p=.364); △ both within-groups □ Fluid intake ↓ (p=.861); △ both within-groups □ Reported QoL-AD↓ (p=.595); ▲ both within-groups (p=.049) □ Observed QoL-AD↑ (p=.387)
		Caregiver outcome	- Adherence to the continence care plan derived (week 16): 68.3% - Caregiver (Nurses, CAs, managers) (qualitative): Resource use/ Quality of continence care/ System utility and limitations

Table 2. Outcomes of Included Studies (Part 2).

1st Author, year	Technology Type	Outcomes	
van Cooten, 2025	Saturation sensing + notification + pattern monitoring + individualized toileting plan	Technical performance	■ Leakages per week: significantly decrease in C compared with E at T2 (p=.01) ■ IM changes per week: significantly reduced in E compared with C at T1 (p=.004) and T2 (p=.003) □ Duration for continence care per week: no significant difference at T1 (p=.89) and T2 (p=.84)
		Patient outcome	□ Subjective well-being (MIPQ): no significant difference at T2 (p=.66) □ Objective well-being (QOL-PMD): no significant difference at T2 (p=.08)
		Caregiver outcome	□ Caregivers' physical burden: no significant difference (p=.09)
Wagg, 2025	Saturation sensing + notification	Technical performance	□ Daily number of pad checks (p=.589) □ Daily number of pad changes (p=.070) □ Daily number of toilet visits (p=.506) □ Daily number of clothing changes (p=.134) □ Daily number of linen changes (p=.703) □ Care efficiency score: reduced more in E (−16 vs −30 min/day) ■ Daily total absorbency: significantly reduced in E (p=.034) □ Time between notification of pad saturation and pad change (p=.346) □ Number of unnecessary checks/changes per 24 hours (p=.218)
		Patient outcome	□ Skin health (p=.209); non-inferiority demonstrated (p<.001) □ Intermittent skin score (p=.209) □ EQ-5D VAS (p=.236) □ QoL-AD score (p=.403) □ Daily responsive behavior score (p=.444) ■ Daily number of sleep interruptions: significantly reduced in E (p=.018)
		Caregiver outcome	□ UWES total score (p=.930) □ Organizational headroom: no significant difference
Yu, 2014	Voiding detection + volume estimation system + pattern monitoring + individualized toileting plan	Technical performance	N/R
		Patient outcome	▲ Volume of urine voided into continence aids ↓ (p=.015) ▲ No. of prescribed toileting events ↓ (median 18→15/72h, p=.015) ▲ No. of actual toileting events (median 6→16/72h, p<.001) ▲ No. of successful toileting events (median 3→8/72h, p=.011) △ % of successful toileting events (50%→50%, unchanged)
		Caregiver outcome	▲ Compliance with care plan prescription (33.3→106.7%, p=.033)

Note.

■ = statistically significant difference between groups

□ = no statistically significant difference between groups

▲ = statistically significant change from baseline (pre–post within-group change)

△ = no statistically significant change from baseline

ADL = activities of daily living; C = control group; CAs = care aides; CI = confidence interval; CMC = Continence Monitoring Chart; E = experimental group; EQ-5D VAS = EuroQol 5-Dimension Visual Analog Scale; IAD = incontinence-associated dermatitis; ICIQ-LUTSqol = International Consultation on Incontinence Questionnaire–Lower Urinary Tract Symptoms Quality of Life; ICIQ-UI Short Form = International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; IM = incontinence material; MIPQ = Mood, Interest and Pleasure Questionnaire; N/R = not reported; NS = not significant; PIADS = Psychosocial Impact of Assistive Devices Scale; QOL-PMD = Quality of Life of Persons with Profound Multiple Disabilities; QoL-AD = Quality of Life in Alzheimer's Disease; T0 = baseline; T1 = first follow-up; T2 = second follow-up; UI = urinary incontinence; UWES = Utrecht Work Engagement Scale.

care planning offers a conceptually different approach by using accumulated voiding data to inform toileting schedules, product selection, and care timing. Studies incorporating this approach suggest potential to support proactive care planning (Rajabali et al., 2023; van Cooten et al., 2025; Yu et al., 2014), although the evidence remains limited. Further research is therefore needed to determine whether this approach can reduce reliance on uniform fixed schedules and align UI care with recommendations for individualized management (Nambiar et al., 2022; Newman et al., 2019).

Regarding technical performance, the included studies evaluated both direct device performance and outcomes derived from technology use. Direct device performance showed mixed findings. This variability may reflect differences in sensing mechanisms and real-world conditions, as sensor measurements can be affected by movement, body position, and pressure changes (Kim et al., 2024). Performance assessment was also limited because one study analyzed only a subset of all recorded voiding events (Cho et al., 2021) and reliance on participant-completed diaries in another (Long et al., 2015). Accordingly, the available evidence is insufficient to draw firm conclusions about the accuracy and reliability of these devices. Among outcomes derived from technology use, positive changes were reported in selected measures of pad checking, leakage, absorbent product use, and costs (Agholme et al., 2023; Rajabali et al., 2023; Wagg et al., 2025). For example, Rajabali et al. (2023) reported a significant reduction in nighttime pad costs, suggesting that sensor-derived information may help caregivers select absorbent products more appropriately and reduce unnecessary product use. This is clinically relevant because appropriate product use and timely pad changing may reduce waste while also helping to prevent prolonged moisture exposure and related skin problems (Kottner & Dissemond, 2025). Given the need for long-term UI management, studies evaluating both clinical and economic outcomes over extended periods are needed to determine the feasibility of implementing these technologies in real-world care settings.

For patient outcomes, positive findings were reported for skin condition, continence-related outcomes, and sleep interruptions. Their interpretation is limited because the skin findings were largely descriptive (Agholme et al., 2023; Cho et al., 2021), continence-related improvements were primarily based on within-group changes (Nikoletti et al., 2004; Yu et al., 2014), and reduced sleep interruptions were reported in only one study (Wagg et al., 2025). Regarding the patient psychosocial outcomes, favorable findings were reported only by Long et al. (2015), including perceived benefits for confidence and a reduced impact of UI on travel. This difference may reflect population and setting heterogeneity. Long et al. (2015) included community-dwelling women who could operate the device and respond directly to alerts, whereas most other studies involved care-dependent individuals who relied on caregivers for UI care (Rajabali et al., 2023; van Cooten et al., 2025; Wagg et al., 2025). Although UI has consistently been associated with reduced quality of life and increased psychosocial burden (Pizzol et al., 2021), the included studies showed limited evidence of improvement in these outcomes. The intervention periods may have been insufficient to capture measurable patient-level changes, particularly among care-dependent populations. Long-term intervention studies that account for the characteristics of the target population are needed to evaluate the effects of sensor-based UI management on quality of life and psychosocial well-being (Gröning et al., 2024; van den Bosch et al., 2025).

For caregiver outcomes, positive findings were reported regarding device usability. Consistent improvements were not observed in caregiver burden, work engagement, or organizational headroom (van Cooten et al., 2025; Wagg et al., 2025). Qualitative findings also indicated implementation barriers, including device malfunction, lack of time, resistance to practice change, and limited organizational support (Nikoletti et al., 2004; Rajabali et al., 2023). Meaningful improvements in caregiver outcomes may require integration into existing workflows, clear staff roles, adequate training, and organizational support (Freeman et al., 2025; Gröning et al., 2024; Walzer et al., 2025). Caregiver outcomes in the included studies were assessed mainly among formal caregivers, including care aides, nurses, and frontline care staff. Evidence regarding informal caregivers remains limited, despite their important role in UI care in community and home settings. This gap carries clinical relevance. UI is associated with broad health consequences and substantial socioeconomic costs across care settings (Bishop

et al., 2025; Soysal et al., 2023). Caregiving related to UI management may place physical, emotional, and time-related burdens on informal caregivers (Akpinar et al., 2023; Bishop et al., 2025). Future studies should evaluate sensor-based UI technologies in home-based care and include outcomes such as caregiving burden, sleep, psychological well-being, and quality of life.

One notable finding of this review was that patient perspectives on usability and satisfaction were insufficiently examined. The only study that collected direct patient feedback was Long et al. (2015), which included community-dwelling women who could operate the device independently and respond directly to its alerts. There is a lack of comprehensive evaluation of patients' usability, satisfaction, or acceptability among patients receiving caregiver-assisted continence care. This gap may limit understanding of how these technologies are experienced by the individuals most directly affected by their use. Patient perspectives on comfort, bodily privacy, dignity, perceived usefulness, and willingness to continue use are essential for determining their clinical relevance. Future studies should conduct patient-centered evaluations among individuals who receive caregiver-assisted continence care but can communicate their experiences, while using adapted methods for those with cognitive or communication impairments.

Limitation

This study is significant in that it integrated the functional characteristics, clinical effects, and caregiver experiences of sensor-based UI technologies and demonstrated that these technologies may serve not merely as urine detection devices, but as tools that support UI care processes and caregivers' decision-making. However, this review has several limitations. First, substantial heterogeneity in the functional components of the interventions and outcome measures across the included studies precluded meta-analysis and required reliance on narrative synthesis, which may limit the integrated interpretation of the evidence. Second, because this review excluded device development and technical validation studies, it may not fully reflect the diversity of technologies in the early development stage or recent advances in sensor-based UI care technologies. Third, this review included only studies published in English, which may have introduced language bias. Fourth, considering the methodological limitations identified in the risk-of-bias assessment and the predominance of pilot/feasibility studies and single-arm designs, confidence in the overall evidence remains limited. Finally, some included studies evaluated commercially developed technologies and involved manufacturers in study funding or conduct, which may have introduced potential conflicts of interest.

Conclusion

This systematic review synthesized evidence on sensor-based UI technologies across technical, patient, and caregiver domains. These technologies are evolving from simple wetness detection toward systems that integrate real-time notification, voiding pattern analysis, and automatic individualized care planning. Technical performance remained inconsistent, and improvements in patient outcomes were limited. Evidence of potential benefit was more apparent for care-process outcomes and support for UI care decision-making than for broader patient outcomes. Individuals requiring diaper-based UI care represent a highly dependent population, and improvements in care processes may have substantial clinical significance even when measurable changes in broader patient outcomes are not observed.

Future research should prioritize standardized outcome measurement, longer follow-up periods, adequate sample sizes, and the inclusion of informal caregivers as a stakeholder group. The cost implications of these technologies, including absorbent product use, staff time, device costs, and sustainability in routine care, should also be evaluated. Rigorous assessment of implementation processes will be important to determine whether these technologies can produce sustained improvements in clinical and long-term care practice.

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