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The impact of humanising hospital care on health outcomes: an observational study protocol

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Abstract

Background The humanisation of care has emerged as a crucial element in contemporary healthcare, with several countries adopting the concept of patient and family-centred care. This change signifies an ongoing evolution within contemporary healthcare, emphasising person-centred approaches, patient autonomy and preferences. The humanisation of care extends beyond patients to include their families and healthcare professionals, to enhance health outcomes, clinical safety, accessibility and therapeutic relationships holistically. This project aims to evaluate the humanisation of care in hospital settings in southern Spain, examining its impact on health outcomes and identifying areas for improvement.

Methods The research employs a three-year multiphase approach, combining cross-sectional designs, qualitative-quantitative analyses and psychometric assessments. The study involves a diverse sample population, including patients admitted to several hospitals in southern Spain along with nursing professionals. Data collection incorporates a range of validated tools, items developed ad hoc and sociodemographic variables.

Discussion The study findings are expected to offer insight into healthcare management, clinical practice and education. Humanising care has the potential to positively impact health outcomes, and the study methodology may serve as a model for future research and educational programmes in healthcare. Whilst acknowledging its limitations, the study represents a critical step in evaluating the humanisation of care in Spanish hospitals and informing strategies for improvement. In conclusion, this comprehensive study addresses the humanisation of care in hospital settings, examining its dimensions and potential impact on health outcomes. The findings may influence policy decisions, emphasising the need to enhance the humanisation of care as a fundamental aspect of healthcare management.

Trial registration NCT06174844 (18/12/2023).

Keywords Humanisation of care, Patient-centred care, Health outcome, Healthcare management, Hospital, Staff outcome

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Background

The humanisation of care has become a key element in healthcare in recent years. Therefore, countries such as the United States, Canada, Australia, Sweden, Norway and Finland have incorporated the concept of "patient and family-centred care" [1]. A recent systematic review identified the main models of patient- and family-centred care, and the findings indicate a lack of studies describing the impact of these models on health outcomes [2]. The consideration of the family and the patient as core elements in the nursing discipline has a historical trajectory; thus, theoretical models such as those proposed by Ida Orlando with Nursing Process Discipline Theory, Marth Rogers with the Theory of Unitary Human Beings, or Jean Watson with the development of the Philosophy and Science of Caring, already showed interest in care centred on the person and their family, as aspects to avoid the dehumanisation of care [3].

Humanising health care entails transitioning from a traditional biomedical and often paternalistic model to a more autonomous person-centred model that respects patients' choices and preferences. Similarly, it is not only aimed at users of the health system, but also affects their families and the health professionals who treat them [4, 5] Therefore, it is about involving users, families, managers and health professionals in a bid to improve health outcomes in terms of clinical safety, accessibility and therapeutic relationships, all from a holistic perspective [6]. In this sense, the humanisation of care has been conceptualised as an empathetic and respectful approach to patients, sufficient human and material resources in healthcare institutions and a balanced workload for healthcare providers. As such, it considers relational, structural and organisational dimensions [7].

Considering the conceptual framework around the humanisation of care, in 2006 McCormack and McCance created the *Person-Centred Care Model*, which reflects the ideals of humanistic care in which there is a moral component, which is translated through relationships that are built into effective interpersonal processes. This model is based on the principles of treating people as individuals, respecting their rights as a person, building mutual trust and understanding, and developing positive relationships [8]. In this regard, a recent systematic review emphasised the contextual environment, the influence of leadership and the nurse-patient relationship in providing fundamental care [9]. In 2010, Kitson, Conroy and others developed a new conceptual model called the *Fundamentals of Care* Framework [10] which acknowledges the centrality of the nurse-patient relationship, along with two other dimensions: integration of care (physical, social and emotional needs of the person and their family) and care context (physical, human resources, structure and organisation) [11].

On this basis, humanising care is expected to have a positive impact on health outcomes [12]. Health outcomes refer to the health consequences caused by the treatment or provision of care in relation to a health condition or because of an interaction with the healthcare system [13]. They involve adverse events, readmissions, mortality rates, safety and well-being among others [14] The World Health Organization predicts that by 2050, people aged 65 and older will account for 33% of the world's population, thus quadrupling the number of octogenarians and nonagenarians [15]. Not surprisingly, in Europe, almost 55% of all hospital stays involve patients over 65 years of age [16]. Most of these patients suffer from chronic diseases and present some level of complexity, which puts them at risk of being frail. Such frail patients who present greater, more complex care needs are challenging the process of care in acute hospitals around the world [17]. Regarding the relational dimension, the nurse-patient relationship has been shown to have an impact on health outcomes, such as adherence to treatment, improvement of stress and, indirectly, on the prevention of adverse events related to healthcare processes [18, 19]. Some studies describe this nurse-patient interaction from the user's perspective, although they are not specific to the current situation of health services with high demand for chronic patients or to emergency demands [20–22].

Existing research does not indicate the extent to which some variables in the care setting, such as the nurse-patient ratio or the type of shift, can affect or predict the occurrence of adverse events such as mortality, pressure injuries or nosocomial infections, which affect user satisfaction with the care received and their comfort during it [23, 24] The study of staff outcomes, such as the perception of the work environment, the level of burnout, job satisfaction and intention to leave, and their relationship with the quality of care provided are widely discussed in the scientific literature. The 'Nurse Forecasting: Human Resources Planning in Nursing -RN4CAST (Grant ID: 223468)' project, which analysed 488 hospitals in 12 European countries (Belgium, England, Finland, Germany, Greece, Ireland, Holland, Norway, Poland, Spain, Sweden and Switzerland), with a sample of close to 34,000 nurses, showed that in hospitals with a higher patient/nurse ratio, the perception of the quality of care provided was poor or fair. The values ranged between 18% in Poland to 4% in Switzerland. Regarding the occurrence of adverse events, such as mortality or pressure injuries, the data ranged from 47% in Greece to 11% in Ireland [25].

In this international context, Andalusia's Regional Department of Health and Families, in southern Spain, has developed the Humanisation Plan for the Andalusian Public Health System, as a strategy aimed at humanising

healthcare in hospitals and primary care [26]. The plan considers three dimensions in healthcare that must be addressed in relation to humanisation: (a) The relational dimension emphasises the critical nature of nurturing therapeutic relationships and promoting transparent and empathetic communication between patients and healthcare providers. By prioritising trust and collaboration, this dimension seeks to empower patients to actively participate in their care decisions and enhance overall satisfaction and outcomes; (b) In addressing the structural dimension, it is essential to meticulously assess and optimise staffing levels, ensuring that healthcare facilities are adequately resourced to meet patient needs effectively. The equitable allocation of resources, including personnel, equipment and facilities, plays a pivotal role in creating an environment conducive to delivering patient-centred care that is both efficient and of high quality. (c) Concurrently, the organisational dimension focuses on implementing tailored protocols and clinical pathways designed to cater to the unique needs of patients while also streamlining operational workflows. Emphasis is placed on fostering a culture of collaboration and teamwork among healthcare professionals from diverse disciplines, thereby promoting synergistic efforts towards achieving optimal patient outcomes. Through these initiatives, healthcare organisations can cultivate environments that prioritise patient well-being and satisfaction while optimising clinical efficiency and effectiveness [26]. Furthermore, the Plan for the Humanisation of the Andalusian Public Health System meticulously describes various weaknesses within the current healthcare framework that require attention. These encompass challenges regarding accessibility, including issues related to disability or fragility that impede equitable access to the healthcare system without risks or adverse events for patients. Moreover, there is a pressing need to enhance patient comfort within healthcare settings, ensuring environments that are conducive to healing and patient well-being. The plan also underscores the imperative need for a steadfast commitment to quality across all facets of healthcare delivery, from diagnosis to treatment and ongoing management. Additionally, it highlights the dearth of comprehensive evaluation mechanisms to gauge the efficacy and impact of implemented interventions accurately. Furthermore, the escalating demand for healthcare services, particularly concerning the exacerbation of chronic illnesses and the demographic shift towards an ageing population, poses a substantial threat to the sustainability and efficacy of the healthcare system [26].

In this context, it is necessary to study and characterise the humanisation of hospital care provision, considering the structural, organisational and relational areas. It is hypothesised that the improvement of these three dimensions should have a positive impact on the expected health outcomes, as well as facilitate the design of intervention strategies and changes in the healthcare system, in the interests of economic efficiency, user satisfaction and quality of the service provided.

AIM

This project aims to evaluate the humanisation of care provided in hospital settings in southern Spain, considering the structural, organisational and relational dimensions, to identify their impact on health outcomes and areas of improvement.

The objectives of the study are to:

1) Evaluate the impact of variables related to relational, structural and organisational dimensions and health outcomes.
2) Quantitatively describe the patient's experience of the healthcare provided.
3) Evaluate the nurse-patient relationship and staff outcomes, as well as their impact on anxiety levels, sleep quality and pain levels from the perspective of the patient.
4) Design and validate a predictive model with the variables involved in the occurrence of adverse events.
5) Design and validate a specific clinical pathway for frail people in Hospital Emergency Departments.

Methods

Design

The research project will be carried out over three years to achieve the following objectives:

Objectives 1 and 2: cross-sectional designs based on questionnaires.

Objective 3: cross-sectional design based on questionnaires and psychometric cut-offs, in three phases: (1) adaptation of the Caring Nurse-Patient Interactions Scale tool through an expert panel and Delphi consensus technique; (2) field study; (3) psychometric study and statistical analysis.

Objective 4: qualitative-quantitative cross-sectional design in three phases: (1) identification of variables related to the occurrence of adverse events and Delphi consensus technique; (2) field study; (3) statistical validation of the predictive model.

Objective 5: qualitative-quantitative psychometric cut-off design in three phases: (1) adaptation of the INICIARE tool through an expert panel and Delphi consensus technique; (2) field study; (3) design and validation of the clinical pathway through a new expert panel and Delphi technique.

Table 1 Study variables and outcomes

Tool	Health outcomes
Patients	
INICIARE scale [27, 28]	Care dependency level, sleep quality, and pain level
Tilburg frailty indicator [29]	Frailty
Caring nurse-patient interaction scale (CNPI) [30]	Nurse-patient interaction
Goldberg scale [31]	Anxiety levels
Athens Insomnia scale [32]	Sleep quality
Picker patient experience scale [33]	Information process and participation in decision-making
Adverse events	Ad hoc items: pressure injuries, falls, catheter infection, mortality, mortality after 30 days of discharge, days of admission and re-admissions
Nursing professionals	
Burnout assessment tool [34]	Burnout
Nursing stress scale [35]	Work stress
Practice environment scale-nursing work index (PES-NWI) [36]	Work environment
Nursing-interactions in caring_competence assessment (NIC_CA) [37]	Caring interaction competence
Intention to leave [38, 39]	Intention to leave nursing work
Turnover intention [38, 39]	Intention to leave the hospital department
Leadership style scale [40]	Nursing director's leadership style

Population and sample

The study population will consist of patients admitted to the following hospitals in the south of Spain: Hospital Virgen del Rocío, Hospital Virgen Macarena, Hospital de Valme, and Hospital San Juan de Dios de Bormujos, in Seville; Hospital Virgen de las Nieves in Granada; Hospital Reina Sofía in Córdoba; Hospital Puerta del Mar and Hospital San Carlos in Cádiz.

Convenience and consecutive sampling will be carried out which includes all adult patients admitted to the Emergency Departments of the aforementioned hospitals, and patients admitted to the Internal Medicine Departments on the specified sampling days. The total required sample size is 2,906 patients, considering a 95% confidence level and 5% precision, with a replacement rate due to successes in the sample of 25%.

Subjects who present cognitive impairment and/or functional diversity will also be included in the sample, subject to prior consent. This consent may be given by the individuals themselves in the case of sensory deficit with preserved cognitive functions or by a representative of the person, such as a companion or legal guardian. In clinical situations involving a low level of consciousness or psychomotor disturbances, consent will also be obtained through representation. Patients who at the time of data collection are haemodynamically unstable or in an emergency condition will be excluded from the study sample.

The sample of nursing professionals will consist of registered nurses and nursing assistants, subject to prior consent, providing care in the Emergency and Internal Medicine units of the hospitals participating in the study. The total required sample size is 378 subjects, considering a 95% confidence level and 5% precision, with a replacement rate due to successes in the sample of 25%.

Both sampling strategies will be implemented over 6 months.

Variables and outcomes

Data will be collected from patients and nursing professionals (registered nurses and nursing assistants). In both groups, sociodemographic data will be collected: age, sex, ethnicity, hospital and department. In the case of patients, the reason and date of admission and whether they need a caregiver will also be collected. In the case of professionals, the professional category, duration in hours and type of shift – day, night or rotating – and number of patients in their care will also be collected.

The assessment tools that will also be used for patients and professionals are summarised in Table 1, as are the outcomes that will be assessed in the sample of patients and the sample of nursing professionals.

The INICIARE scale (*Inventario del NIvel de Cuidados mediante IndicAdores de clasificación de Resultados de Enfermería*) stratifies subjects into four groups based on the care dependency level: high dependency, moderate dependency, risk of dependency and independence. The scale was developed in Spain and has demonstrated construct validity with eight factors, criterion validity and external validity (Cronbach's alpha 0.92) [27, 28]. In addition, some of its items, taken independently, assess pain level and sleep quality.

The Tilburg Frailty Indicator is a dichotomous qualitative scale assessing the presence of frailty. There is a

validated version in Spain, which demonstrated optimal reliability values (Cronbach's alpha 0.97) [29].

The Caring Nurse-Patient Interactions (CNPI) scale was developed through a rigorous process of cultural adaptation and construct validation, demonstrating excellent psychometric properties (Cronbach's alpha 0.97). Moreover, the items comprising it comprehensively include behaviours and attitudes related to caregiving interactions, with a particular focus on the nurse's consideration of the patient's preferences, wishes, desires and spiritual matters [30]. Our research team conducted the cultural adaptation of the 70-item CNPI scale and obtained its translation into Spanish [41].

The Goldberg Anxiety and Depression Screening is a validated questionnaire in Spain with two subscales, one for anxiety and one for depression. Each subscale consists of four initial screening items to determine the likelihood of a mental disorder, followed by a second group of five items that are only asked if positive responses are obtained to the screening questions. The Spanish version achieved a sensitivity of 83.1%, a specificity of 81.8% and a positive predictive value of 93.5% [31].

The Athens Insomnia Scale is a brief instrument with eight items to assess difficulties in sleeping and measure the daytime impact caused by insomnia. The Spanish version showed a high degree of internal consistency, obtaining a Cronbach's alpha of 0.90 [32].

The Picker Patient Experience Scale explores patients' perceptions of the information process and participation in decision-making during hospital admission. The Spanish version obtained high internal consistency (Cronbach's alpha of 0.792) [33].

Regarding the study of staff outcomes, the following validated scales have been identified in the Spanish context: Burnout Assessment Tool, which evaluates the presence of burnout, with Cronbach's alpha values between 0.79 and 0.89 for its dimensions [34]; Nursing Stress Scale, which assesses anxiety among nursing professionals, with a Cronbach's alpha of 0.92. It consists of 32 items grouped into 9 dimensions [35]; the Practice Environment Scale-Nursing Work Index (PES-NWI), which measures the work environment in nursing practice, with a Cronbach's alpha of 0.90. It comprises 30 items grouped into 5 dimensions [36]; and the Nursing Interactions_ Competence Assessment Tool (NIC_CA-Prof). This tool consists of 15 items that predict and measure competence in the development of caregiving interactions in registered nurses, with a particular focus on the nurses' consideration of the patient's preferences, wishes, desires and spiritual matters. The reliability and composite reliability values of the predictive model are greater than 0.7 [37]. Concerning the Leadership Style scale, which measures staff perception regarding the leadership style and capability of a manager within a company, it was validated in Spanish with a Cronbach's alpha of 0.96 [40]. In the present study, the psychometric validation of this scale will be conducted in the healthcare context.

Concerning the Intention to Leave and Turnover Intention scales, for which there is no published Spanish validation, these are two brief scales with 2 items each that have already been used in other studies in Spain [42]. In this study, the Spanish translations used in these previous studies will be employed.

Data collection

The following phases will be implemented for data collection:

a) A phase of cross-cultural adaptation of the INICIARE Scale, Frailty and Sleep quality measures, and the Caring Nurse-Patient Interaction scale will be carried out. The consensus technique will be conducted through an expert group (8–10 nurses) with over 10 years of professional experience in hospital emergency care and management, having knowledge of nursing methodology, taxonomy and/or care for patients at risk of dependency or frailty. The expert panel sample will be identified with the assistance of the Nursing Directors of the participating hospitals. Once the list of potential experts meeting the mentioned inclusion criteria is obtained, the research team will send them a formal invitation, along with project information and objectives via email. As many validation rounds and meetings as required will be performed.
b) Design and configuration of the survey. A pilot study will be conducted with the preliminary version of both surveys -patients and nursing staff- to assess their understanding and completion time.
c) Recruitment of nurses for data collection.
d) A presentation session for the study will be designed and implemented, along with training in surveys and the completion process, for each of the participating hospitals. Nursing professionals recruited for data collection will attend this session.

LimeSurvey© software will be used for data collection. Online surveys will be designed, containing all the variables and outcomes described. Thus, concerning patient data, a survey will be designed for the Emergency Department and another for Internal Medicine; concerning staff data, a survey will be designed for registered nurses, in which the variable "work unit" will be controlled, and another for nursing assistants. To access the online survey items, nursing professionals should indicate their reading and acceptance of the informed consent to participate in the study on the survey platform.

Patient data collection will be hetero-administered in the Emergency and Internal Medicine Departments of the participating hospitals. The nurses trained to collect data will complete an online survey containing all study variables through a direct survey with the patient at their bedside. Data will be collected from all patients admitted to the same Department on each sampling day to ensure rigor in the results of the association between staff outcomes and health outcomes.

In contrast, the collection of data from registered nurses and nursing assistants will be self-administered. Registered nurses and nursing assistants will complete the online survey during their shift, without disrupting care in any way, on the hospital unit computers. The online data collection survey will contain an initial section describing the objectives of the project and an opt-in and informed consent form, which must be accepted to access the survey items. Data will be collected from all nursing professionals once each sampling day. To this end, the study research team will contact the Directors of Nursing to explain the study and request their help in disseminating the link to the survey for professionals on specific sampling days.

Concerning mortality data 30 days after hospital discharge, the research team will collect this information a posteriori, by consulting the patient's medical records, with the prior consent of the patient or their legal representative.

Statistical analysis

Regarding the cross-cultural adaptation and validation of scales, exploratory factor analysis will be conducted following Bartlett's test of sphericity and a Kaiser-Meyer-Olkin test using SPSS v29 [43]. Construct validity will be assessed through principal component extraction and orthogonal and non-orthogonal rotation. Confirmatory factor analysis will be performed using AMOS v23.0 [44], calculating the Chi-square statistic and adjusted goodness of fit indices (AGFI), normed fit index (NFI), comparative fit index (CFI), relative fit index (RFI) and root mean square error of approximation (RMSEA) to test the model's goodness of fit. For criterion validity, the results from the Tilburg Frailty Indicator and Athens Insomnia Scale will be used to design ROC curves and calculate sensitivity and specificity.

Additionally, descriptive, univariate, and bivariate analysis of the study variables will be carried out, preceded by an analysis of data distribution normality using the Kolmogorov-Smirnov test, using SPSS v29. Statistical regression analyses are expected to be conducted to quantify the mediating effect of sociodemographic variables in the sample, such as gender or ethnicity. In addition, mean scores of the assessment scales will be obtained on the data collected from nursing professionals for each sampling day. These scores will be correlated with the mean scores of the patient assessment scales for each sampling day, to run regression models. In this way, through beta coefficients, the correlation between both data sources will be studied. For the design of predictive models, partial least squares regression and multiple regression models will be run using SPSS v29 and ADANCO 2.4 [45].

Ethical considerations

Ethical aspects that ensure compliance with Organic Law 3/2018, of December 5 on the Protection of Personal Data and Guarantee of Digital Rights will be taken into account [46]. Furthermore, when conducting this research, the Declaration of Helsinki will be considered, as ratified in 2014 [47]. Ethical approval has been obtained from the Ethics Committee of the Andalusian Regional Government (0840-N-22).

During the study, informed consent will be requested from both patients and nursing professionals, following the following principles:

- The voluntariness of participants will be ensured after informing them of the study's objectives. In cases where the user cannot provide consent due to cognitive impairment and/or health conditions and has been identified as a subject of this study, representation consent will be considered.
- Confidentiality and professional secrecy, as required by professionals, will be maintained in all cases.
- Participants will be offered the option to withdraw voluntarily from participating in the study at any time.
- Informed consent will be sought from nurses recruited for data collection from both users and professionals, and it is necessary to acknowledge this premise to proceed with the completion of the online questionnaire.

Discussion and implications

Major advancements have been achieved in healthcare in recent decades to enhance the quality, efficiency and safety of medical care. Although these improvements have positively impacted certain aspects of patient care, they also present challenges. Automation, standardisation and fragmentation of care pathways can lead to dehumanisation, treating patients as mere collections of symptoms [7]. Additionally, healthcare professionals, frequently assessed solely based on their professional performance, may be perceived as liabilities rather than valuable assets. This dynamic can have consequences for both the well-being of professionals and the overall effectiveness of the healthcare system [48].

The scientific, political and educational impact of the project

The proposed study has significant implications for healthcare management, clinical practice and university education in the field of healthcare. Firstly, within the realm of healthcare management, the study findings could provide valuable insights into the humanisation of care in hospital settings. By examining the structural, organisational and relational dimensions of care, health managers can better understand the factors that influence patient outcomes and satisfaction. Patient satisfaction levels are a crucial healthcare outcome, considered a determinant measure of the quality of care.

[49]. Health outcomes have been defined as changes in health status that occur as a result of a health-related event, illness or healthcare intervention [50]. Therefore, they can be regarded as indirect indicators of the humanisation of healthcare, understood not only in terms of relational aspects of care but also as structural and organisational aspects, as they occur through exposure to the healthcare system [51].

From a clinical practice perspective, the study's results could delineate how healthcare professionals engage with patients. Understanding the impact of nurse-patient relationships and organisational context on health outcomes would facilitate the provision of more patient-centred care [52]. Healthcare professionals could become more aware of the importance of communication, empathy and teamwork in achieving positive health outcomes, leading to improved patient experiences and overall quality of care. This knowledge, in turn, could serve as a foundation for the ongoing training of healthcare professionals to develop and refine their interpersonal skills and clinical competencies.

Furthermore, the implications of the study extend to university education in the healthcare field. The research project's methodology may serve as a model for research and education programmes in healthcare higher education. It underscores the importance of evidence-based practice and the need for rigorous research to inform decisions in the health domain. In addition, the results obtained should highlight the need to improve the humanisation of care, as it is hypothesised to have an impact on health outcomes. Therefore, it is once again evidence-based knowledge that should be incorporated as a cross-cutting competence in nursing training programmes [53, 54].

The main limitation of the study is the lack of control over the homogeneity of the practices in different participating hospitals. There is a general trend marked by existing standards, although the slight variability in their application is a fact. However, the study represents a preliminary approach to evaluating the humanisation of care in Spanish hospitals, serving as a starting point for the development of new strategies and improvement plans.

Conclusion

In conclusion, the proposed study provides a comprehensive approach to understanding and improving the humanisation of care in hospital settings, with broad implications for healthcare management, clinical practice and healthcare education. By investigating the structural, organisational and relational dimensions of healthcare, this research has the potential to provide objective data on the humanisation of care that may influence policy decisions in healthcare management.

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Author contributions

APG and RAC contributed to the initial conception and design of the study; AMPG, RAC, YAMM, and MDQG contributed to the further development of the study design. AMPG, RAC, YAMM and MDQG drafted the manuscript; AMPG, RAC, YAMM and MDQG made critical revisions to the paper for intellectual content. All authors approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study has received ethical approval from the Andalusian Regional Government Ethics Committee (0840-N-22), as well as participating hospitals. Informed written consent is a requirement.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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