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Validity, reliability and psychometric properties of the Italian version of the Nurses' Cancer Pain Management Competency Scale

Vincenzo Damico[1], Manuela Pedrini[1], Giuseppe Demoro[2], Luca Cossalter[1], Liana Murano[3], Antonella D'Alessandro[4], Lara Fermi[5], Margherita Milani[6], Giuseppe Russello[7], Viola Margosio[8]

Keywords: Nurses' Cancer Pain Management Competency Scale; reliability; validity; cancer pain
Parole chiave: Scala della competenza infermieristica per la gestione del dolore da cancro; affidabilità; validità; dolore da cancro

Abstract

Background and aim. *The Nurses' Cancer Pain Management Competency Scale (NCPMCS) is a tool to explore nurses' competencies and subjective experiences in cancer pain management, and to help nurses understand their current shortcomings in cancer pain management in medical oncology departments. In the hypothesis that cancer pain is not a problem exclusively specific to the oncology context, we tested the psychometric characteristics of the scale on the general Italian nurses population.*

Methods. *A cross-sectional design was used in which a sample of nurses was enrolled from 16 hospital in Northern, Southern and Central Italy. A convenience sampling method was used to recruit Italian nurses who met the eligibility criteria completed the study for developing the Italian version of the Nurses' Cancer Pain Management Competency Scale. Internal consistency was assessed using Cronbach's alpha, and construct validity was examined using exploratory factor analysis. Data collection took place in July 2024.*

Results. *The sample involved 128 nurses who met the inclusion criteria. The sample was predominantly female (68%). The factor loads of the NCPMCS ranged between 0.81 and 0.92, and the t value was greater than 1.96 for all 14 items. On a 4-point scale for total competency, the mean score was 1.94 ±0.81. The multidimensional nature of pain (2.01 ±0.93) was the factor that showed the highest mean score, whereas the management of pain factor was the lowest (1.87 ±0.83). The Cronbach's alpha of the scale was 0.806 and ranged from 0.719 to 0.836.*

The results showed that the chi-square degree of freedom ratio was 2.662, the goodness-of-fit index was 0.854, the root mean square of approximate error was 0.037, the value-added fitting index was 0.876, the comparative fitting index was 0.928.

Conclusion. *The scale is valid and reliable for the evaluation of nursing competencies in managing cancer pain even among nurses who do not work in medical oncology departments.*

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Introduction

Many people are affected by cancer, and its prevalence is increasing as the population is aging (1). Pain is a common symptom of cancer diagnosis and rises in prevalence throughout and beyond cancer treatment (1).Pain caused by cancer takes many forms. It may feel dull, painful, sharp, or burning. It can be constant, intermittent, mild, moderate or severe (2). Mild pain may be uncomfortable and noticeable, but it does not interfere with normal daily living activities. Specifically, mild pain can be barely noticeable and easily ignored (1). Moderate pain begins to hinder daily life. Specifically, moderate pain cannot be ignored for more than a few minutes. Severe pain can make the patient unable to carry out normal daily living activities (1). Specifically, severe pain requires attention and prevents you from performing tasks and functions. It may interfere with restful sleep pattern, limit physical activity, and even make conversation difficult (1).

The amount of pain experience depends on a number of factors, including the type of cancer, how advanced it is, where it is located, and your pain tolerance (1). Most cancer pain is manageable, and pain control is an essential part of treatment (2).

In a recent review, a total of 52 studies were selected for the meta-analyses on pain and pain severity in the different stages of cancer disease (1). Pain prevalence rates were 39.3% after cancer treatment 55.0% during anticancer treatment and 66.4% in advanced, metastatic, or terminal disease. Moderate to severe pain was reported by 38.0% of all patients in studies that included all cancer stages (1). Cancer pain needs to be appropriately managed because pain interferes with patients' social and psychological wellbeing (2), and unrelieved pain causes negative clinical consequences (3).

Patients are greatly impacted by the physical and psychological suffering they experience as well as fatigue and depression (4). As one of the most prevalent symptoms experienced by cancer patients, pain can impact a patient's life status, perceived quality of life, psychological well-being, and illness beliefs. In fact, patients with stage III and stage IV cancers generally report severe pain (5).

Pain is more prevalent (86%) among patients with stage III and IV cancer, who have anxiety (63%) and metastasis (76.4%) (5). Of the patients with cancer pain, 68%, 13%, and 19% experience mild, moderate, and severe pain, respectively (5). The highest proportion of cancer pain was seen in patients with gastrointestinal cancer (30%) followed by those with hematologic cancer (21%) (5).

Although currently no studies seem well to describe the association between pain and depression among cancer patients, cancer pain if undertreatment will worsen patients' psychological anguish and depressive feelings (6). It will also have a number of detrimental impacts, including the development of fear-avoidance beliefs, a drop in treatment compliance, and even an impact on patients' treatment and prognosis value (6).

An essential component of the pain management team is oncology nurses, and as a result, managing cancer pain presents significant challenges for nurses (7). Assessing nurses' current cancer pain management competency and effectively developing personalized training programs are of great significance in improving nurses' cancer pain management competency and awareness (8). As of right now, the majority of cancer pain management research and investigation tools are patient-centered, and adequate instruments to assess nurses' cancer pain management proficiency are still lacking (8).

Inadequately managed pain can lead to adverse physical and psychological patient outcomes for individual patients and their families (9). Of particular importance to nursing care, unrelieved pain reduces patient mobility, resulting in complications such as deep vein thrombosis, pulmonary embolus, and pneumonia (7-9). Complications related to inadequate pain management negatively affect the patient's welfare and the hospital performance because of extended lengths of stay and readmissions, both of which increase the cost of care (9).

Nurses' improper assessment and management of pain can lead to patient safety concerns and negative health outcomes. Knowledge of pain is influenced by work specific experience and training. In a recent Italian study (10), improved knowledge and attitudes were observed among nurses who did so attended a pain educational program in the last three years, providing further evidence of validity of a refresher course on pain (10). Participation in continuous professional development (in both formal and informal contexts) is an important component of clinical practice. However, nurses' cancer pain management competency is generally still insufficient (6).

Previous studies measured pain management competency using a self-assessed instrument focused on self-efficacy and knowledge (8).

The Nurses' Cancer Pain Management Competency Scale (NCPMCS) is a recently created new scale

to explore nurses' competencies and subjective experiences in cancer pain management, and to help nurses understand their current shortcomings in cancer pain management (11). The scale is divided into four factors and 14 items. The four factors include Clinical conditions, Pain assessment and measurement, Management of pain, and Multidimensional nature of pain. Each nurse can self-evaluate or be evaluated own skills on a scale score ranging from 0 to 4, with 1 (poor), 2 (average), 3 (good), and 4 (excellent) for each of the 14 items (11). Furthermore, based on the scale's specific score, nurses can evaluate their lack of understanding about cancer pain management, advance research into this area, and enhance their capacity to control cancer pain while providing patient care (11, 12). During 2024, the scale was also validated in Italian using a cohort of 243 nurses from different medical oncology departments across the national territory (13). The cronbach's alpha was 0.814 and the Guttman half-reliability was 0.819 indicating high internal consistency of the scale, strong reliability for evaluating nurses' cancer pain management competency and a good stability across time (13).

Recent developments in oncology, which facilitate better control of tumor growth and thereby reduce the associated phenomena of inflammation, ischemia, and compression, have also contributed to the reduction in cancer pain prevalence and severity, improving the patients' quality of life (14). Targeted treatments have also increased patients' survival and, for some patients, have led to a disease-free outcome. Consequently, a novel population of patients called "cancer survivors" has emerged (14). According to a recent systematic review, 47% of cancer survivors report the presence of some chronic pain (moderate to severe pain: 28%) in relation to previous treatments like chemotherapy, radiotherapy, or curative surgery or even in relation to a concomitant chronic pain condition unrelated to cancer or cancer treatment (14). Experiencing pain and insufficient relief can be devastating and negatively affect a patient's quality of life (13-14). Developments in oncology such as new treatments and adjusted pain management guidelines may have influenced the prevalence of cancer pain and severity in patients. Increased attention to the assessment and management of pain might have fostered the decline in the prevalence and severity of pain (14).

The management of chronic pain in this population requires a different approach from that used for individuals with a limited prognosis (14).

A comprehensive clinical examination is needed to distinguish between cancer pain, cancer treatment pain and pain due to comorbid conditions, and to identify the type of underlying pain in order to treat it appropriately (1). Safe, effective and evidence-based management of cancer-related pain is a cornerstone of comprehensive cancer care. Advances in the early detection, diagnosis and treatment of cancer enable patients to survive longer, and an increasing number of healthcare professionals consider cancer to be a disease for which a chronic course can be achieved (2, 4). This means that comprehensive pain management must also be continued for a longer period of time and is essential for patients to maintain an adequate quality of life (5, 10-11). This requires a multidisciplinary approach to the management of pain in cancer survivors, in which community nurses and general practitioners play an important role, especially once a patient has been cured of cancer, but may still experience chronic pain. Pain assessment continues to remain an essential focus of nursing practice (10). Nurse's role is challenging, she must demonstrate that she is clinically proficient and competent (6). Nurses have to use creative assessment skills, clinical judgment, psychological support, advocacy, and good communication skills in such a way that the contribution of drugs, nursing care, and other nonpharmacological treatments are maximized to the patient's benefit (3-5). Nurses' role in controlling cancer pain include believing the patient, assessing pain, identifying the root of the problem, planning the care, administering medication, evaluating effectiveness, ensuring good pain control, and individualizing treatment (11). Patient's or family's beliefs and attitudes toward cancer pain are substantial in pain management (6).

In the hypothesis that cancer pain is not a problem exclusively specific to the oncology context, we tested the psychometric characteristics of the NCPMCS on the general Italian nurses population. Secondary objective was to compare the scores of the scale between nurses educated in pain management versus those who were not educated and to test the stability of the scales over time among nurses who did not work in a medical oncology department.

Methods

Design, Sample, Procedure

A cross-sectional design was used in which a sample of nurses was enrolled from 16 hospital and university centers in the provinces of Lecco, Milan, Como, Bergamo, Varese, Siena, Florence, Grosseto,

Rome, Potenza, Messina, Reggio Calabria, Taranto, Palermo, Catania and Caltanissetta.

To be enrolled in the study, healthcare workers had to be clinical nurses with at least 2 years of work experience. Nurses with less than 2 years of experience or non-clinical nurses (e.g. nurse coordinators) were excluded.

A convenience sampling method was used to recruit Italian nurses who met the eligibility criteria completed the study for developing the Italian version of the Nurses' Cancer Pain Management Competency Scale.

The collection of information took place via an online form. The inclusion criteria were verified and guaranteed with an initial question. Before starting to fill out the questionnaire, the nurses had to indicate that they were nurses with at least 2 years of work experience and that they carried out their professional activity in a clinical context (this excluded nursing coordinators). If the nurse clicked the *'Yes'* he could proceed with filling in the socio-demographic data and the questionnaire. If they answered *'No'*, our application did not give the possibility to proceed with completing the questionnaire.

Data collection

Data collection was conducted from July 1st to July 30th, 2024 and was conducted by 6 nurses through the administration of an online questionnaire via Google Form (15) as explained below.

Thirty days after initial data collection, nurses not working on medical oncology departments were telephoned for readministration of the NCPMCS to assess test-retest reliability.

These nurses received training on the aims and protocol of the study and were trained by the first author to collect data using an excel dataset.

The first author was always available by telephone during data collection and met every 2 weeks via Google Meet (16) with data collectors to monitor study progress.

With permission from the hospital administration, the research team distributed questionnaires via computerized software (Google Form) (15) already used for previous studies (10, 13). The authors provided the department group an electronic questionnaire with a link.

An email was sent to 11 nursing coordinators with the invitation to send the questionnaire to their nurses.

Attached to the email was a short letter which explained the project and a link to click to access the compilation of the questionnaire was sent. The email was presented by the five main authors. The information is then collected and automatically connected to a spreadsheet. The spreadsheet is populated with the survey and quiz answers. The editors were V.D. and L.M. Participants responded to the survey on a voluntary basis. The answer to the survey was considered a written consent participate.

Questionnaires

The questionnaire is made up of individual and multiple choice questions and is structured in two sections (a total of 21 items).

The first section concerned the collection of the nurses' general characteristics were surveyed using a self-administered questionnaire covering age, sex, academic degree, workplace location, position, duration of their nursing career, experience in the current department and pain management training, work in an oncology department or not (7 items).

The second section concerned the administration of the Nurses' Cancer Pain Management Competency Scale (NCPMCS) (14 items) (11, 12). The NCPMCS is designed to assess clinical nurses' competency in managing cancer pain. The scale is divided into 4 dimensions and 14 items. The 4 dimensions include Clinical conditions, Pain assessment and measurement, Management of pain, and Multidimensional nature of pain. There were 5 items describing nurses' competency to establish pain management strategy and carry out pain health education in time, 5 items describing nurses' competency to assess and measure cancer pain, 2 items describing their competency to manage cancer pain, and 2 items describing nurses' competency to understand the multidimensional nature of cancer pain. All items is assigned a score ranging from 0 to 4, with 1 representing very difficult (poor), 2 representing some what difficult (average), 3 representing almost complete (good), and 4 representing very good (excellent). A higher score indicated the nurse's competency to manage cancer pain. The Cronbach's α of the original scale was 0.890, and the Cronbach's α of each factor was 0.690-0.830 (12).

The Italian validation was carried out by Damico and colleagues in 2024 (13).

The group completed the questionnaire anonymously after being informed of the pertinent privacy principles and measures. However, we requested telephone contact or email to contact the nurses of the departments outside medical oncology for a re-test 30 days later ensure the completeness

and quantity of the questionnaire, the researchers checked whether there were omissions and errors in the completed questionnaires.

Low-quality data such as too short questionnaire filling time and excessive overlap of item frequency were excluded from the audit process.

Data analysis

A descriptive analysis was used to study the frequency distribution of all variables of interest. For normally distributed data, mean and standard deviation (SD) were applied.

Descriptive statistics were calculated to summarize quantitative data. The internal consistency reliability was identified using Cronbach's alpha (α). Exploratory factor analysis with principal component analysis and varimax rotation was used to investigate the construct validity of the NCPMCS.

Pearson correlation coefficient was calculated by the critical ratio method and correlation coefficient method for item analysis, and the scale reliability was described by Cronbach's coefficient, Guttman split-half reliability.

Item level content validity index (I-CVI) and Scale level content validity index (S-CVI) in the expert evaluation were adopted. S-CVI evaluated the content validity of the scale and evaluated the structural validity of the scale through exploratory factor analysis and confirmatory factor analysis. The test level is $\alpha = 0.05$.

The factorial structure of the scale was examined using confirmatory factor analysis (CFA) for each separate NCPMCS scale, a crucial step in construct validity testing. Testing of the theoretical assumptions began with an examination of the factor structure of the Italian version of the NCPMCS (17).

The discriminant validity of the NSPMCS was established by comparing a subgroup of nurses who had received pain-assessment/management education with another subgroup who had not. Because the small number of nurses in both groups, the nonparametric Mann-Whitney U test was used for this analysis (12).

Reliabilities for each factor and each scale derived from the CFA were estimated using factor score determinacy coefficients (12, 17). These coefficients represent an estimate of the internal consistency of the solution, the certainty with which factor axes are fixed in the variable space (12). They represent the squared multiple correlations (SMCs) of factor scores predicted from scores on observed variables (18).

In a good solution, SMCs range between 0 and 1; the larger the SMCs, the more stable the factors. A high SMC (say, .70 or better) means that the observed variables account for substantial variance in the factor scores. A low SMC means the factors are poorly defined by the observed variables.

The reliability of the NCPMCS was also tested with the intraclass correlation coefficient (ICC). This coefficient gives an estimate of the test-retest stability of the scale scores; thus, it provides complementary information to that given by the internal consistency reliability.

Additionally, exploratory factor analysis of the study was performed using the KMO test and the 2 value of Bartlett's spheroid test to examine the strength of the partial correlation (how the factors explain each other) between the variable and for measures sampling adequacy for each variable in the model and the complete model.

The P value was fixed at .05. Statistical analysis was performed using SPSS 21.0 software package (19), except for the CFA, which was performed with Mplus 6.1 (20) as already used for another validation study (21).

Ethical considerations

Nurses who showed interest for the study were recruited and asked to sign the informed consent prior to participating in the study and completing the questionnaires. The study questionnaire was introduced to each participant, and for each participant was asked to answer the questions. The study protocol was in line with the Declaration of Helsinki, as revised in 2013 (22).

The nurses belonging to the different geographical area and departments completed the survey and were offered the possibility to remain anonymous. Data were collected in completely anonymous form. Therefore, the approval of an Ethics Committee was not necessary and the GDPR EU 2016/678 in force in Italy since 2018 does not apply for our study design (23).

Results

Sample

Of the 200 hypothetical nurses, 128 completed measures of sociodemographic characteristics and measures of nursing competency in cancer pain management. Of the responding nurses, 83.6% (n=107) did not work in a medical oncology department. The sample was predominantly female (68%), the average

Table 1 - General Characteristics of Italian nurses sample (N= 128).

Variable	Results
Age (year)	
Mean, SD	39.3 (± 10.6)
Range, n, %	
25-29	9 (7.1)
30-39	77 (60.2)
40-49	3 (2.3)
50-60	39 (30.4)
Sex n, %	
Male	41 (32)
Female	87 (68)
Level of Education n, %	
Diplome in Nursing	26 (20.3)
Bachelor's Degree in Nursing	102 (79.7)
Master's Degree in Nursing Science	49 (38.3)
1st level Master degree	31 (24.2)
Department n, %	
Oncological department	21 (16.4)
Other department	107 (83.6)
Refresher course on pain for the last 5 years[1] n, %	
Yes	39 (30.4)
Not	89 (69.6)
Work experience (year)	
Mean (SD)	12.6 (+ 7.2)
Range n, %	
2-4	13 (10.2)
5-10	79 (61.7)
11-19	12 (9.3)
20-30	24 (18.8)

[1] It includes participation in courses, conferences and research relating to pain in the last 5 years.

age was 39 years and 79.7% had a Bachelor's Degree in Nursing. Work experience was approximately 13 years (Table 1).

Pain Management Educational Needs/Resources.

Of the 128 nurses, 39 (30.4%) nurses had received pain management training in the last five years, and 53 (41.4%) had no available protocols related to pain management in their work department. The most preferred educational modality was simulation-based learning for 115 nurses (89.8), followed by web-based learning for 12 nurses (9.3%) and skills practice for 1 nurses (0.8%).

Confirmatory factor analysis of the Nurses' Cancer Pain Management Competency Scale.

Figure 1 gives a graphical description of the final nurses' cancer pain management competency model,

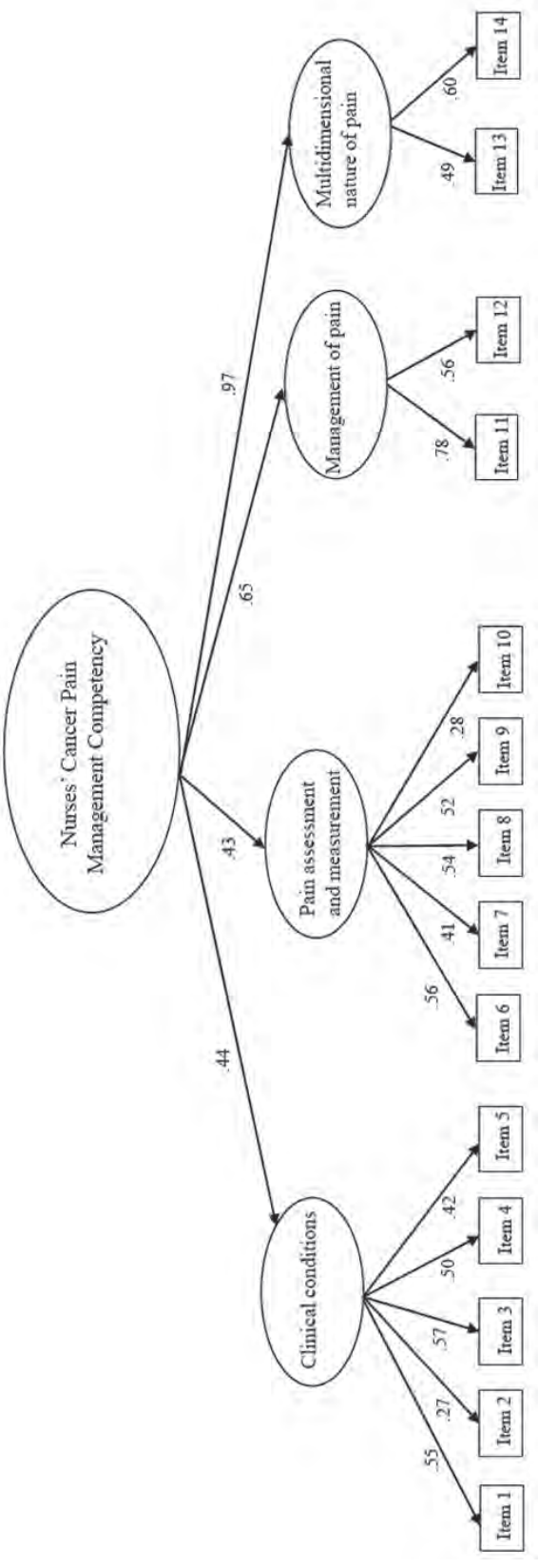

Figure 1 - Confirmatory factor analysis of the Nurses' Cancer Pain Management Competency Scale.

which fit the data well. The analysis was carried out only among nurses who did not work within a medical oncology department (n= 107).

The results showed that the chi-square degree of freedom ratio ($\chi 2$ /df) was 2.662, the goodness-of-fit index (GFI) was 0.854, the root mean square of approximate error (RMSEA) was 0.037, the value-added fitting index (IFI) was 0.876, the comparative fitting index (CFI) was 0.928. This model shows that the factorial structure of the nurses' cancer pain management competency scale, although multidimensional at the level of primary factors, is unidimensional at the level of the secondary, higher order factor.

As seen in the path diagram, the original structure of the NCPMCS was accepted without any modification. The factor loads of the NCPMCS ranged between 0.81 and 0.92, and the *t* value was greater than 1.96 for all 14 items.

Reliability of the Nurses' Cancer Pain Management Competency Scale.

The Cronbach's alpha of the scale was 0.806 and ranged from 0.719 to 0.836. On a 4-point scale for total competency, the mean score was 1.94 ±0.81. The multidimensional nature of pain (2.01 ±0.93) was the factor that showed the highest mean score, whereas the management of pain factor was the lowest (1.87 ±0.83). The Guttman half-reliability of the scale was 0.831.

As regards the individual items of the competency scale, the highest score emerged regarding item 5 (*Monitor effects of pain management approaches to adjust the plan of care as needed*) average score = 2.07 (0.78) while the lowest score regarding item 7 (*Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population*), an average score of 1.86 (0.79) emerged (Table 2).

Scale Validity Analysis

The item content validity index (I-CVI) of this scale was 0.811- 1.000, and the S-CVI value was 0.921, based on the results of the expert consultation. Additionally, the study's exploratory factor analysis revealed that the KMO test value was 0.828 and the Bartlett's spheroid test $\chi 2$ value was 2156.347 ($p<$ .001), meeting the requirements for the analysis. The factors were extracted using principal component analysis, then the maximum variance method was utilized to rotate the factors. They extracted common components with eigenvalue > 1 and factor load value > 0.400. Four common factors in all were extracted, according to the results, and no items were removed. The cumulative variance contribution rate was found to be 72.459%, and the factor load value of the 14 items in their dimensions ranged from 0.811 to 0.873, which was consistent with the original scale.

Table 3 shows the comparison between the mean scores of educated versus noneducated nurses over 5 years in pain management.

Educated nurses reported feeling more competent than uneducated nurses regarding competence 1(implement an individualized pain management an that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources) p < .001; competence 3 (explain how health promotion and self-management strategies are important to the management of pain) p< .001; competence 6 (assess patient preferences and values to determine pain-related goals and priorities) p= .002; competence 9 (explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain) p< .001; competence 10 (demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care) p< .001; competence 11 (develop a treatment plan that considers the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life) p< .001 and competence 12 (explain how to assess and manage pain across settings and transitions of care) p< .001.

Stability of the NCPMCS

Table 4 shows the test-retest reliability (stability) of the NCPMCS. This analysis was done with the complete sample and repeated in the subgroup of nurses who did not work in a medical oncology department. The ICCs were calculated for each factor and scale. All ICCs demonstrated excellent test-retest reliability, with most of values greater than 0.90 for every factor and scale.

Test-retest reliability was calculated with the ICC correlating the Nurses' Cancer Pain Management Competency Scale scores collected twice with a 30-day interval between testing. Test-retest for the nurses pain management competency was computed only with 107 non-medical oncology nurses at both intervals. P< .001 for each correlation. Abbreviations: 95% CI, 95% confidence interval; ICC, intraclass correlation coefficient.

Table 2 – Descriptive Statistics for Individual Factors of the Nurses' Cancer Pain Management Competency Scale (N= 128).

Factors	Mean	SD	Min	Max
I. Clinical conditions				
1. Implement an individualized pain management an that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.	1.91	0.84	1	4
2. Describe the role of the nurse as an advocate in assisting patients to meet treatment goals.	2.02	0.87	1	4
3. Explain how health promotion and self-management strategies are important to the management of pain.	2.00	0.78	1	4
4. Present theories and science for understanding pain.	1.94	0.76	1	4
5. Monitor effects of pain management approaches to adjust the plan of care as needed.	2.07	0.78	1	4
II. Pain assessment and measurement				
6. Assess patient preferences and values to determine pain-related goals and priorities.	1.87	0.80	1	4
7. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.	1.86	0.79	1	4
8. Describe the unique pain assessment and management needs of special populations	1.96	0.78	1	4
9. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.	1.91	0.79	1	4
10. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.	1.95	0.77	1	4
III. Management of pain				
11. Develop a treatment plan that considers the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.	1.85	0.75	1	4
12. Explain how to assess and manage pain across settings and transitions of care.	1.90	0.71	1	4
IV. Multidimensional nature of pain				
13. Describe the impact of pain on society.	2.03	0.85	1	4
14. Define terminology for describing pain and associated conditions.	1.96	0.90	1	4

Discussion

This is one of the first studies testing an instrument for measuring the nurses' Cancer Pain Management Competency not only in oncological setting.

In this study, we demonstrated that the NCPMCS is a valid and reliable method of measuring the cancer pain management competency among nurses.

The dimensionality of the NCPMCS was analyzed by means of one CFA. This CFA was conducted on the items defining each 1 of the 4 scales comprising the NCPMCS (clinical conditions, pain assessment and measurement, management of pain and multidimensional nature of pain). The goodness-of-fit indices supported the hypothesized models. These analyses showed a complex and interesting structure of the index. The scales showed a hierarchical structure, with several valid and reliable primary factors corresponding to narrow dimensions that allow a fine-grained assessment of nurses' cancer pain management competency and valid and reliable higher order factors that support the conventional use of total scores for a more global assessment.

The CFA of this scale allowed the identification of an autonomous management factor but showed also a narrower provider-directed management factor, with low factor loadings that question its validity. More research is needed for a deeper understanding of this result, but it could be a cultural phenomenon reflecting the treatment norms in Italy on pain assessment and management.

In this study, the Italian version of the Nurses'

Table 3 – Comparison of Mean Scale and Factor Scores Between Nurses Educated on pain assessement/management Versus Nurses Not Educated during the last 5 years.

Factors	Educated nurses (n= 39)	Noneducated nurses (n= 89)	Mean difference	t-value	P
I. Clinical conditions, mean (SD)					
1. Implement an individualized pain management an that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.	2.43 (0.75)	1.67 (0.75)	0.76	-5.2790	**<.001**
2. Describe the role of the nurse as an advocate in assisting patients to meet treatment goals.	2.12 (0.76)	1.97 (0.91)	0.15	-0.8974	.185
3. Explain how health promotion and self-management strategies are important to the management of pain.	2.48 (0.64)	1.78 (0.74)	0.70	-5.0922	**<.001**
4. Present theories and science for understanding pain.	2.07 (0.70)	1.91 (0.81)	0.16	-1.2721	.205
5. Monitor effects of pain management approaches to adjust the plan of care as needed.	2.20 (0.69)	2.02 (0.84)	0.18	-1.1913	.235
II. Pain assessment and measurement, mean (SD)					
6. Assess patient preferences and values to determine pain-related goals and priorities.	2.56 (0.67)	1.70 (0.78)	0.86	-3.7829	**.0002**
7. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.	1.92 (0.73)	1.84 (0.81)	0.08	-0.5308	.596
8. Describe the unique pain assessment and management needs of special populations	2.15 (0.54)	1.88 (0.87)	0.27	-1.7624	.080
9. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.	2.23 (0.77)	1.78 (0.77)	0.45	-2.8197	**.005**
10. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.	2.38 (0.63)	1.76 (0.77)	0.62	-4.4225	**<.001**
III. Management of pain, mean (SD)					
11. Develop a treatment plan that considers the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.	2.31 (0.52)	1.65 (0.75)	0.66	-4.9295	**<.001**
12. Explain how to assess and manage pain across settings and transitions of care.	2.28 (0.64)	1.74 (0.69)	0.54	-4.11463	**<.001**
IV. Multidimensional nature of pain, mean (SD)					
13. Describe the impact of pain on society.	1.82 (0.72)	2.13 (0.70)	-0.31	1.70496	.090
14. Define terminology for describing pain and associated conditions.	2.17 (0.82)	1.86 (0.73)	10.31	-1.81807	.071

Cancer Pain Management Competency Scale was introduced as an effective assessment tool to provide reference for cross-sectional investigations and cancer pain management interventions and we also tested the validity, reliability and applicability of the scale among Italian nurses, regardless of the clinical context. To date, most of the research and survey tools on cancer pain management in the world are patient- and oncology-focused, and adequate tools to assess nurses' competence in cancer pain management are still lacking (1, 2, 4). The Italian version of the NCPMCS can be a useful tool for evaluating nurses' competence in managing cancer pain. Different departments can conduct individualized training to improve nurses' cancer pain management competency, enhance evidence based pain management programs, and support nurses in regularly self-evaluating their cancer pain management competency, all in accordance with current pain management guidelines and the unique characteristics of cancer pain. Low cancer pain management competency among nurses may have detrimental effects on patients' outcomes and

Table 4 – Test-Retest Reliability of Nurses' Cancer Pain Management Competency Scale(Full Sample and only nurses who did not work in a medical oncology department).

Factors	ICC (95% CI)	
	Full sample (n= 128)	Only non-medical oncology nurses (n= 107)
I. Clinical conditions		
1. Implement an individualized pain management an that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.	0.87 (0.84-0.90)	0.93 (0.89-0.94)
2. Describe the role of the nurse as an advocate in assisting patients to meet treatment goals.	0.92 (0.91-0.94)	0.93 (0.91-0.95)
3. Explain how health promotion and self-management strategies are important to the management of pain.	0.93 (0.91-0.94)	0.94 (0.91-0.96)
4. Present theories and science for understanding pain.	0.94 (0.92-0.93)	0.94 (0.92-0.96)
5. Monitor effects of pain management approaches to adjust the plan of care as needed.	0.92 (0.90-0.94)	0.93 (0.90-0.95)
II. Pain assessment and measurement		
6. Assess patient preferences and values to determine pain-related goals and priorities.	0.92 (0.90-0.94)	0.92 (0.90-0.94)
7. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.	0.92 (0.91-0.94)	0.93 (0.91-0.96)
8. Describe the unique pain assessment and management needs of special populations	0.87 (0.83-0.89)	0.92 (0.91-0.95)
9. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.	0.87 (0.84-0.90)	0.93 (0.89-0.95)
10. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.	0.90 (0.87-0.92)	0.92 (0.90-0.94)
III. Management of pain		
11. Develop a treatment plan that considers the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.	0.92 (0.90-0.94)	0.93 (0.91-0.94)
12. Explain how to assess and manage pain across settings and transitions of care.	0.94 (0.91-0.96)	0.94 (0.92-0.96)
IV. Multidimensional nature of pain		
13. Describe the impact of pain on society.	0.92 (0.91-0.94)	0.93 (0.91-0.95)
14. Define terminology for describing pain and associated conditions.	0.94 (0.92-0.93)	0.94 (0.92-0.96)

reduce the efficacy of their cancer pain management practice (13).

Nurses, as a participative advocate for pain management, the nurse's comprehension of cancer pain and the position itself are especially crucial. A thorough evaluation of pain should concentrate on the degree of pain, its location, kind and quality, length, history of the pain, and its radiating effects to other body areas (24, 25).

The study's RMSEA value was 0.037 and its 2 value was 2.662. Analysis revealed that the fitting model created using the scale factors had good goodness of fit, suggesting that the Italian version of the scale had strong structural validity. The Italian version of the NCPMCS scale items was consistent with the measurement dimensions, which verified that the preset dimension structure matched well with the actual data. The consistency and stability of the measured findings can be represented by the scale's dependability; the better the reliability, the more stable and dependable the measuring device (21). The higher the internal consistency, the more accurately the measured topic reflects the research topic, and the stronger the correlation between the items in each dimension. The consistency and stability of the measured findings can be represented by the

scale's dependability; the better the reliability, the more stable and dependable the measuring device (20). The higher the internal consistency, the more accurately the measured topic reflects the research topic, and the stronger the correlation between the items in each dimension. It is generally believed that the Cronbach's α coefficient of the total scale is >0.800, the Cronbach's α coefficient of the subscale is >0.700, and the broken half reliability is >0.800, indicating good reliability. In this study, Cronbach's coefficient was 0.806, and the reliability of each dimension was 0.719 to 0.836 indicating high internal consistency of the scale and strong reliability of the scale for evaluating nurses' cancer pain management competency. At the same time, all ICCs demonstrated excellent test-retest reliability, with most of values greater than 0.90, indicating that the scale has good stability across time.

In contrast to the Korean validation study (11) which showed the lowest score for the pain assessment and measurement factor, the lowest score was obtained for the management of pain factor. The data is in line with our first validation study (13). While the highest score was always obtained for the multidimensional nature of pain factor in line with the results of Hu and colleagues (11) and our first validation study (13).

Regarding the current practice and training needs, although 30% of all nurses had received cancer pain management training, a high percentage of nurses (41%) did not have a cancer pain management-related protocol in their work department. Although the perceived importance and interest in cancer pain management are increasing, there are still insufficient resources to support nurses' cancer pain management practice in clinical settings. As nurses play an integral role in assessing, managing, and evaluating cancer pain, it is critical for nurses to perform cancer pain management proficiently.

Every nurse should be able to assess and manage pain. Nurses play a critical role in effective pain management because they have frequent contact with patients and are responsible for assessing and managing their pain (26). Adequate pain assessment and management have significant consequences for patients' physical and psychological health (25).

Consistent with previous studies, nurses educated in pain management demonstrated higher responses to the questionnaire which emphasizes the importance of nursing education in the field of pain (26, 27). Pain education interventions influence outcomes sensitive to nursing care (26, 27). Nursing pain care and documentation, audit and feedback to nurses, benchmarking, and pain education programs or protocols influence pain documentation. pain, pain evaluation, pain reappraisal and satisfaction (27). However, pain education strategies vary widely between studies (27), which used multivariate interventions without sufficient systematization or opportunities to transfer study protocols as such (27). It would be useful to standardize on a common strategy regarding a training plan for pain nursing specific to macro areas (e.g. critical care, palliative care, surgery, oncology). Nurses performed better on pain management after participating in training using action learning and online learning (11, 28), and the presence of a protocol in the work setting was shown to improve nurses' pain management competency (29). Therefore, it is necessary to adopt an in-hospital protocol for cancer pain management that is based on current clinical practice guidelines or reviews (30-32) that nurses can refer to at any time, along with competency-based training that can promote nurses' cancer pain management competency. Furthermore, nurses in the present study preferred multi-component educational modalities with the highest simulation-based learning experience.

Limit

The first and most important limitation is the convenience and non-random sampling model, which makes the results influenced by the strict selection of cases. Random sampling would have allowed the instrument to be validated in a more heterogeneous nursing group.

This may have influenced the averages that emerged in the responses, as it is likely that the respondents were the greatest number of nurses motivated by the management of cancer pain and therefore offered the best responses.

Being the first study in Italy that tried to evaluate nursing skills in managing cancer pain, we had difficulty comparing our results and we do not know how generalizable they are.

It is currently not possible to perform the criterion control verification of the local version of the scale, nor are there any other relevant instruments or translated versions available to assess the cancer pain treatment competence of nursing personnel in Italy. We should broaden the sample size and geographical reach of nurses in the future, add to the validation analysis, and investigate the use of this scale in Italy.

We consider our study design as a limitation due to its inability to establish causal relationships and its focus on analyzing potential predictors.

Additionally, acknowledge that the self-assessment tool may introduce response biases influenced by social desirability. Studies using randomized sampling and able to establish causal relationships by focusing on the analysis of potential predictive factors are necessary.

Furthermore, it is likely that nursing skills in cancer pain management reflect the legislative and regulatory context in Italy and the validity of the questionnaire may be different in other European contexts.

Conclusion

The Nurses' Cancer Pain Management Competency Scale, which includes 14 assessment items and 4 dimensions in the "Italian version", is appropriate to evaluate the competence of clinical nurses in the management of cancer pain in the Italian context not only among medical oncology departments. The scale is valid and reliable for the evaluation of nursing competencies in managing cancer pain even among nurses who do not work in medical oncology departments.

To date, the tool is reliable for evaluating the skills of clinical nurses in the treatment of cancer pain. In addition to being a useful tool for clinical settings, this questionnaire makes it easy for researchers to learn more about the general degree of competence in cancer pain management that clinical nurses in Italy possess or lack. The NCPMCS measures competence and may be useful in assisting faculty in developing a pain management program to promote competence in pain management.

Training is a cornerstone in improving nursing knowledge and skills as emerged in the average scores we compared between educated and uneducated nurses. Training programs that utilize multicomponent education and experiential learning are needed to achieve optimal competence in cancer pain management in nurses.

Authors' contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript. In particular,VD First author, principal investigator, project manager; MP translation of the questionnaire into Italian; GD: Direct participation in the writing and revision of the article, Dissemination of the questionnaire; LC and LM: Direct participation in the writing and revision of the article, Dissemination of the questionnaire; AD: Writing study protocol and writing results section and tables; LF: Language translation review; MM: revision of manuscript; GR, VM Dissemination of the questionnaire.

Riassunto

Validità, affidabilità e proprietà psicometriche della versione italiana della Nurses' Cancer Pain Management Competency Scale

Introduzione e obiettivo. La Nurses' Cancer Pain Management Competency Scale (NCPMCS) è uno strumento nato per esplorare le competenze e le esperienze soggettive degli infermieri nella gestione del dolore da cancro e per aiutare gli infermieri a comprendere le loro attuali carenze nella gestione del dolore da cancro nei reparti di oncologia medica. Nell'ipotesi che il dolore da cancro non sia un problema esclusivamente specifico del contesto oncologico, abbiamo testato le caratteristiche psicometriche della scala sulla popolazione infermieristica italiana generale.

Metodi. È stato utilizzato un disegno trasversale in cui è stato arruolato un campione di infermieri provenienti da 16 ospedali del Nord, Sud e Centro Italia. È stato utilizzato un metodo di campionamento di convenienza per reclutare gli infermieri italiani che soddisfacevano i criteri di ammissibilità e hanno completato lo studio per lo sviluppo della versione italiana della Nurses' Cancer Pain Management Competency Scale. La coerenza interna è stata valutata utilizzando l'alfa di Cronbach e la validità di costrutto è stata esaminata utilizzando l'analisi fattoriale esplorativa. La raccolta dati è avvenuta nel mese di luglio 2024.

Risultati. Il campione ha coinvolto 128 infermieri che soddisfacevano i criteri di inclusione. Il campione era prevalentemente femminile (68%). I fattori di caricamento della NCPMCS variavano tra 0.81 e 0.92 e il valore *t* era maggiore di 1.96 per tutti i 14 elementi. Su una scala a 4 punti per la competenza totale, il punteggio medio era 1.94 ±0,81. La natura multidimensionale del dolore (2.01 ±0.93) è stato il fattore che ha mostrato il punteggio medio più alto, mentre la gestione del fattore dolore è stata il più basso (1.87 ±0.83). L'alfa di Cronbach era 0.806 e variava da 0.719 a 0.836.

I risultati hanno mostrato che il rapporto del grado di libertà chi quadrato era 2.662, l'indice di bontà di adattamento era 0.854, la radice quadrata media dell'errore approssimato era 0.037, l'indice di adattamento era 0.876, l'indice di adattamento comparativo era 0.928.

Conclusioni. La scala risulta valida ed affidale per la valutazione della competenze infermieristiche nella gestione del dolore da cancro anche tra gli infermieri che non lavorano nei reparti di oncologia medica.

References

1. van den Beuken-van Everdingen MH, Hochstenbach LM, Joosten EA, Tjan-Heijnen VC, Janssen DJ. Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. J Pain Symptom Manage. 2016 Jun;**51**(6):1070-1090.e9. doi: 10.1016/j.jpainsymman.2015.12.340. Epub 2016 Apr 23. PMID: 27112310.

2. Webb JA, LeBlanc TW. Evidence-based Management of Cancer Pain. Semin Oncol Nurs. 2018 Aug;**34**(3):215-226. doi: 10.1016/j.soncn.2018.06.003. Epub 2018 Aug 10. PMID: 30100369.
3. Baratta JL, Schwenk ES, Viscusi ER. Clinical consequences of inadequate pain relief: barriers to optimal pain management. Plast Reconstr Surg. 2014 Oct;**134**(4 Suppl 2):15S-21S. doi: 10.1097/PRS.0000000000000681. PMID: 25254999.
4. Coveler AL, Mizrahi J, Eastman B, Apisarnthanarax SJ, Dalal S, McNearney T, et al. Pancreas Cancer-Associated Pain Management. Oncologist. 2021 Jun;**26**(6):e971-e982. doi: 10.1002/onco.13796. Epub 2021 May 12. PMID: 33885205; PMCID: PMC8176967.
5. Kibret AA, Wolde HF, Moges AM, Aragie H, Teferi ET, Assefa YA, et al. Prevalence and associated factors of cancer pain among adult cancer patients evaluated at an oncology unit in the University of Gondar Comprehensive Specialized Hospital, northwest Ethiopia. Front Pain Res (Lausanne). 2023 Feb;**17**(3):1061239. doi: 10.3389/fpain.2022.1061239. PMID: 36874932; PMCID: PMC9982129.
6. Bouya S, Balouchi A, Maleknejad A, Koochakzai M, AlKhasawneh E, Abdollahimohammad A. Cancer Pain Management Among Oncology Nurses: Knowledge, Attitude, Related Factors, and Clinical Recommendations: a Systematic Review. J Cancer Educ. 2019 Oct;**34**(5):839-846. doi: 10.1007/s13187-018-1433-6. PMID: 30315497.
7. Jung MY, Matthews AK. Understanding nurses' experiences and perceptions of end-of-life care for cancer patients in Korea: A scoping review. J Palliat Care. 2021 Oct;**36**(4):255-264. doi: 10.1177/08258597211027021. Epub 2021 Jun 29. PMID: 34182840.
8. Hassan S, Stevens B, Watt-Watson J, Switzer-McIntyre S, Flannery J, Furlan A. Development and initial evaluation of psychometric properties of a pain competence assessment tool (PCAT). J Pain. 2022 Mar;**23**(3):398-410. doi: 10.1016/j.jpain.2021.09.002. Epub 2021 Sep 25. PMID: 34583019.
9. Al-Atiyyat N, Salim NA, Tuffaha MG, Abu Nigim HA, Saleh MM, Alkhodary ME, et al. A Survey of the Knowledge and Attitudes of Oncology Nurses toward Pain in United Arab Emirates Oncology Settings. Pain Manag Nurs. 2019 Jun;**20**(3):276-283. doi: 10.1016/j.pmn.2018.08.005. Epub 2018 Dec 7. PMID: 30527855.
10. Damico V, Murano L, Macchi G, Forastieri Molinari A, Dal Molin A. Knowledge and attitude of pain management among Italian nurses in intensive care unit: a multicentric descriptive study. Ann Ig. 2021 May-Jun;**33**(3):220-230. doi: 10.7416/ai.2021.2429. PMID: 33739355.
11. Luo H, Li Q, Xu R, Han S, Yang J. Reliability and Validity of the Chinese Version of the Nurses' Cancer Pain Management Competency Scale. Pain Manag Nurs. 2024 May 10:S1524-9042(24)00142-5. doi: 10.1016/j.pmn.2024.04.003. Epub ahead of print. PMID: 38734526.
12. Hu JY, Roh YS. Psychometric Evaluation of the Nurses' Cancer Pain Management Competency Scale. Pain Manag Nurs. 2023 Apr;**24**(2):209-215. doi: 10.1016/j.pmn.2022.08.009. Epub 2022 Sep 25. PMID: 36171159.
13. Damico V, Demoro G, Cossalter L, Murano L, D'Alessandro A, Fermi L, et al. The Italian version of the the Nurses' Cancer Pain Management Competency Scale: a validation study. In press. Ann Ig. 2025 Mar-Apr; **37**(2). In press.
14. Mestdagh F, Steyaert A, Lavand'homme P. Cancer Pain Management: A Narrative Review of Current Concepts, Strategies, and Techniques. Curr Oncol. 2023 Jul 18;**30**(7):6838-6858. doi: 10.3390/curroncol30070500. PMID: 37504360; PMCID: PMC10378332.
15. Google Inc. Google Forms. Available from: https://www.google.com/forms/about/ [Last accessed: 2024 Sep 30].
16. Google Inc. Google Meet. Available from: https://meet.google.com/ [Last accessed: 2024 Sep 30].
17. Muthén LK, & Muthén BO. Mplus User's Guide: Statistical Analysis with Latent Variables. 7th ed. Los Angeles, CA: Muthén & Muthén; 2015.
18. Tabachnick BG, Fidell LS. Using Multivariate Statistics. New York, NY: Harper Collins; 1996.
19. IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp; 2021.
20. MPLUS (Version 6.11). [Computer Software]. Los Angeles, CA: Muthén & Muthén.
21. Vellone E, Riegel B, Cocchieri A, Barbaranelli C, D'Agostino F, Glaser D, et al. Validity and reliability of the caregiver contribution to self-care of heart failure index. J Cardiovasc Nurs. 2013 May-Jun;**28**(3):245-55. doi: 10.1097/JCN.0b013e318256385e. PMID: 22760172.
22. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;**310**(20):2191-4. doi: 10.1001/jama.2013.281053. PMID: 24141714.
23. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) (OJ L 119 04.05.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj)
24. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. Res Social Adm Pharm. 2019 Feb;**15**(2):214-221. doi: 10.1016/j.sapharm.2018.03.066. Epub 2018 Mar 27. PMID: 29606610.
25. Kasasbeh MAM, McCabe C, Payne S. Action learning: an effective way to improve cancer-related pain management. J Clin Nurs. 2017 Nov;**26**(21-22):3430-3441. doi: 10.1111/jocn.13709. Epub 2017 Mar 2. PMID: 28032387.
26. International Association for the Study of Pain (IASP). IASP Curriculum Outline on Pain for Nursing. 2021. Available from: https://www.iasp-pain.org/Education/CurriculumDetail.aspx?ItemNumber=2052 [Last accessed: 2024 Sep 30].
27. Melia R, Morrell-Scott N, Maine N. A review of compliance with pain assessments within a UK ICU. Br J Nurs. 2019 Mar 28;**28**(6):382-386. doi: 10.12968/bjon.2019.28.6.382. PMID: 30925247.

28. Grommi S, Vaajoki A, Voutilainen A, Kankkunen P. Effect of Pain Education Interventions on Registered Nurses' Pain Management: A Systematic Review and Meta-Analysis. Pain Manag Nurs. 2023 Aug;**24**(4):456-468. doi: 10.1016/j.pmn.2023.03.004. Epub 2023 Apr 7. PMID: 37032260.
29. Youngcharoen P, Aree-Ue S. A cross-sectional study of factors associated with nurses' postoperative pain management practices for older patients. Nurs Open. 2023 Jan;**10**(1):90-98. doi: 10.1002/nop2.1281. Epub 2022 Jun 28. PMID: 35762683; PMCID: PMC9748055.
30. Fallon M, Giusti R, Aielli F, Hoskin P, Rolke R, Sharma M, et al. Management of cancer pain in adult patients: ESMO Clinical Practice Guidelines. Ann Oncol. 2018 Oct 1;**29**(Suppl 4):iv166-iv191. doi: 10.1093/annonc/mdy152. PMID: 30052758.
31. Swarm RA, Paice JA, Anghelescu DL, Are M, Bruce JY, Buga S, et al. Adult Cancer Pain, Version 3.2019, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2019 Aug; 1;**17**(8):977-1007. doi: 10.6004/jnccn.2019.0038. PMID: 31390582.
32. Damico V, Cazzaniga F, Murano L, Ciceri R, Nattino G, Dal Molin A. Impact of a Clinical Therapeutic Intervention on Pain Assessment, Management, and Nursing Practices in an Intensive Care Unit: A before-and-after Study. Pain Manag Nurs. 2018 Jun;**19**(3):256-266. doi: 10.1016/j.pmn.2018.01.007. Epub 2018 Apr 19. PMID: 29680212.

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Behind closed doors: Freelance nurses and the reality of unmet care needs in Italian home care setting. Insight from a phenomenological descriptive study

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Keywords: Missed care; nursing; territorial; home-based; freelance professionals; phenomenological study
Parole chiave: Missed nursing care; Assistenza domiciliare; Infermieri liberi professionisti; family-centered care

Abstract

Background. *The term 'Missed Nursing Care' (MNC) refers to any aspect of nursing care that is not delivered, partially delivered, or delayed. MNC has significant negative consequences, including adverse patient outcomes, safety risks, and decreased job satisfaction. While extensively studied in hospitals, MNC in community healthcare settings, remains under-researched, especially in Italy. This study aims to explore the phenomenon of MNC in Italian home care settings by documenting and analyzing the lived experiences of freelance nurses, focusing on the characteristics, influencing factors, and consequences of MNC as perceived by these healthcare professionals.*
Study Design. *This is a descriptive phenomenological study.*
Methods. *Using snowball sampling, 12 Italian freelance nurses were recruited and interviewed from November 2022 to February 2023. Data collection was based on in-depth interviews, that have been transcribed and analyzed using Giorgi's phenomenological framework. The study report adhered to the COREQ-32 checklist for qualitative research.*
Results. *Thematic analysis revealed four main themes: dimensions of MNC, organizational challenges, consequences of MNC, and family-nurse collaboration. Freelance nurses frequently addressed unmet fundamental and complex nursing needs, highlighting significant clinical, psychological, and economic impacts on patients and families. Organizational issues, such as rigid public service schedules and inadequate staffing, were identified as primary contributors to MNC. Families played a crucial role in managing care and collaborating with freelance nurses to ensure continuity.*
Conclusions. *This study provides novel insights into MNC in Italian home care settings, emphasizing the critical role of freelance nurses in filling care gaps. The findings suggest the need for systemic changes to improve flexibility, staffing, and integration of public and private nursing services. Further research, particularly quantitative studies, is essential to validate these findings and explore broader implications for patient care and health outcomes.*

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Introduction

The term 'Missed Nursing Care' (MNC) describes any aspect of nursing care that is not delivered, partially delivered, or delayed for various reasons (1). MNC has negative consequences, including inefficient resource utilization, adverse patient outcomes, safety risks, and decreased job satisfaction (1-4). While MNC has been extensively studied in hospitals, research in community healthcare settings, either in Italy or elsewhere, remains limited (5). Understanding the phenomenon and its causes in community healthcare settings is essential for developing effective strategies to address this issue and improve outcomes for patients, staff, and organizations.

Over the last two decades, the global healthcare scenario has undergone significant transformations due to epidemiological changes, advancements in pharmaceuticals and technology, financial constraints, and a global shortage of healthcare professionals. The epidemiological changes and scientific advancements have led to a rising prevalence of chronic diseases, increased life expectancy, often accompanied by growing rates of disability and frailty, and shorter hospital stays (6-8). However, financial constraints and the global shortage of healthcare professionals are making it increasingly difficult for countries to effectively address these challenges (9). In response, national health authorities are increasingly supporting the transition of care from hospitals to community healthcare settings (10,11). In Italy, this transition was significantly accelerated by the COVID-19 pandemic, and community healthcare provision is continuously informed by the National Outcomes Plan, a permanent observatory that provides decision-makers and healthcare professionals with detailed and reliable data on the outcomes of community-based interventions (12). In this context, nurses, as the largest workforce, play a crucial role in the organization and delivery of care. Evaluating their contribution and viewpoints is essential to fully understand the effectiveness of community care (13). For this reason, considering quality indicators of nursing care is important to achieve high-quality care and meet populations' needs. In this regard, one of the internationally recognized proxies of nursing care quality in the community setting is MNC, due to its potential impact on patient safety, rehospitalizations, and overall care quality (5,14). Research conducted in hospital settings has explored the relationship between MNC and patient outcomes and safety, highlighting the role of various organizational and individual factors (14-18) such as staffing levels, organizational issues, working climate, educational level, and competency level. Similarly, evidence from community care settings indicates that MNC is most likely to occur in contexts where human resources and time are limited, although research in this area remains poor (5,19). The complexity and heterogeneity of community care services, characterized by multiprofessional collaborations within a framework of integrated care, pose challenges to the systematic investigation of MNC phenomena (13). Existing findings are limited regarding the role of environmental and organizational factors, as well as the impact of 'out-of-pocket services' on MNC. In Italy, the home care services encompass a comprehensive and personalized range of health care interventions provided by multidisciplinary teams to patients in their own homes (13). Nursing care provided in this context is guaranteed by the public sector. However, patients and their families can supplement nursing care by utilizing services from freelance nurses, social cooperatives, or private companies. This adds a further element of complexity to the investigation of MNC, as not all MNC remains unaddressed if private nurses are called in to fill the gaps left by the public sector. MNC, detected by the public system, may not be perceived as such by the patient when the private sector intervenes. This hidden phenomenon warrants investigation because, on one hand, it introduces a potential bias in the study of MNC within home care services, such as considering missed care that is not actually missed, and on the other hand, it could reveal issues of unequal access to care for patients who lack sufficient financial resources.

In this framework, the primary aim of this study was to describe the lived experiences of freelance nurses involved in instances of MNC within Italian home care services. Through the exploration of their experiences, we sought to uncover characteristics, factors influencing MNC, and its subsequent consequences, as perceived by these healthcare professionals.

Method

Study design

A descriptive phenomenological study was conducted following Husserl's methodology (20, 21) and Giorgi's phenomenological framework for data analysis (22). To integrate these two approaches, Husserl's principles of epoché and phenomenological reduction were employed during the data collection

Table 1 - Interview Guiding Questions

Can you describe any situations where you had to address a patient's care need due to a lack of nursing intervention by other services (e.g. the public one)?
What factors do you believe influenced these situations?
How did these situations impact the patient and their family?
What role did the family or other caregivers have in these situations?
What care interventions did you provide in these situations?

phase to ensure that the participants' experiences were captured in their purest form, free from preconceived notions (23). Subsequently, Giorgi's step-by-step analytical process was applied to these data, providing a systematic means of identifying and describing the essential structures of the experiences. This combination allowed for a rigorous exploration of the phenomena, grounded in Husserl's foundational concepts and enhanced by Giorgi's practical guidance for data analysis.

The report of this study was checked against the COREQ-32 checklist for presenting results in qualitative studies (24).

Participants, and setting

A snowball sample of Italian freelance nurses, providing care mainly at home, were preliminarily contacted by phone to assess their interest in participating in the study. During the call, the nurses were verbally briefed on the concept of MNC and informed about the study's aims and confidentiality (25). Nurses were enrolled if they have been working as freelance nurses for at least two years (26). After having obtained the consent to participate, a female researcher, working as freelance registered nurse conducted the face-to-face audio-recorded interviews through Google Meet from November 2022 to February 2023. In accordance with the phenomenological study design, sample size was not established a priori. Enrolment was ended when data saturation was ascertained, i.e., when no additional data were obtained from the interviews (25).

Procedure and data collection

Nurses who decided to participate were required to fill a semi-structured online questionnaire via Microsoft Forms, covering socio-demographic and professional details (such as gender, age, education level, years of work experience (overall and as freelance nurse), and daily working hours. Subsequently, for each participant, a formal appointment has been arranged with a suitably qualified researcher to conduct qualitative interviews. The interviews were based on five guiding questions (Table 1) developed after a focus group among the researchers and a literature review. Participants received these questions via email before their interviews to allow for self-reflection. The interview was sent with a short cover letter that explained again the study's goals and the concept of MNC. The guiding questions were employed flexibly to broadly elicit nurses' experiences of MNC in the home care setting. Questions were adapted or omitted as needed to encourage participants to share their stories in depth. The interviewer ensured consistency in data collection across participants while allowing for individual variations. Interviews began with a brief socialization period to establish rapport before initiating audio recording. After ensuring participants understood the concept of MNC, they were asked to describe their experiences providing home care, focusing on factors contributing to MNC and its impact on patients and families. To maintain consistency, all interviews were conducted by the same researcher without additional personnel present. Field notes were taken to capture potential insights into participants' experiences as freelance nurses. Following each interview, a debriefing session with other researchers was held to refine the interview process based on emerging findings and study objectives.

Data analysis and trustworthiness

Interviews were transcribed verbatim following Giorgi's phenomenological data analysis framework, comprising bracketing, intuition, analysis, and description (21, 22). Researchers initially bracketed their preconceptions to mitigate bias (27). Subsequently, through immersion in transcripts and field notes, researchers developed an intuitive understanding of participants' experiences. Significant statements were then extracted, clarified, and categorized into emergent themes. Finally, themes were richly described using illustrative quotations with interview references, adhering to phenomenological principles. To enhance rigor, two researchers independently conducted

thematic analysis and triangulated findings (28). No software was used for data management.

To establish trustworthiness as outlined by Guba (29), multiple strategies were employed. The research process was meticulously documented and transparently reported. A single researcher conducted audio-recorded interviews using a snowball sampling technique with nurses. Field notes were collected and used in debriefing sessions to inform subsequent interviews. Rigorous bracketing and triangulation were applied during analysis to maintain objectivity and focus on participants' lived experiences within a phenomenological framework. Results were presented through a detailed thematic analysis, with themes summarized in a table for clarity.

Ethical Issues

The study, approved by the Internal Review Board of the Master of Science in Nursing Program in adherence to local standards, was undertaken as part of a program-related project. All participants provided the informed consent to participate. In accordance with Italian and European laws, participants' anonymity and confidentiality were guaranteed throughout the study.

Results

Participants

Data saturation was reached after interviewing 12 freelance nurses. Table 2 presents participant characteristics in detail. The majority of them were male (n = 9, 75%), with a mean age of 37.7 years (SD = 8.5). Seven participants (58.3%) held a Bachelor of Science in Nursing, while only four (33.3%) achieved a Postgraduate Degree. The average nursing work experience was 14.6 years (SD = 8.0), with an average freelance nursing experience of 7.8 years (SD = 4.9). Participants typically worked approximately 7.4 hours per day (SD = 1.9).

The lived experiences of freelance nurses regarding MNCs in home care settings

The thematic analysis of the interviews' content revealed four themes and ten descriptive categories and were reported in a coding tree (Figure 1). The average duration of the face-to-face interviews was 25 minutes (range 18-45).

Dimensions of Missed Nursing Care

Freelance nurses frequently find themselves addressing gaps in patient care, as they are often contacted by patients and their families to meet needs that have not been adequately addressed by other nurses, particularly those working in public services. This perspective offers a unique insight into the challenges faced by patients and their caregivers and highlights the importance of continuity of care.

Missed nursing care typically manifests in two primary areas: fundamental and complex nursing care. In terms of fundamental nursing care, unmet needs commonly involve patient care related to elimination, medication management, nutrition, and wound care.

Table 2 - Characteristics of participants

ID	Sex	Educational Level	Years of work experience	Years of work experience as FLN	Daily working hours
1	Male	Postgraduate Course	15	10	7
2	Male	Postgraduate Course	18	11	8
3	Male	BSN	24	18	7
4	Female	Postgraduate Course	17	5	6
5	Male	BSN	14	10	7
6	Male	BSN	10	6	9
7	Male	BSN	4	3	7
8	Male	BSN	6	6	5
9	Male	Postgraduate Course	15	4	6
10	Female	Postgraduate Course	31	12	12
11	Male	BSN	1.5	1.5	6
12	Female	BSN	7	2	9

BSN = Bachelor Science in Nursing

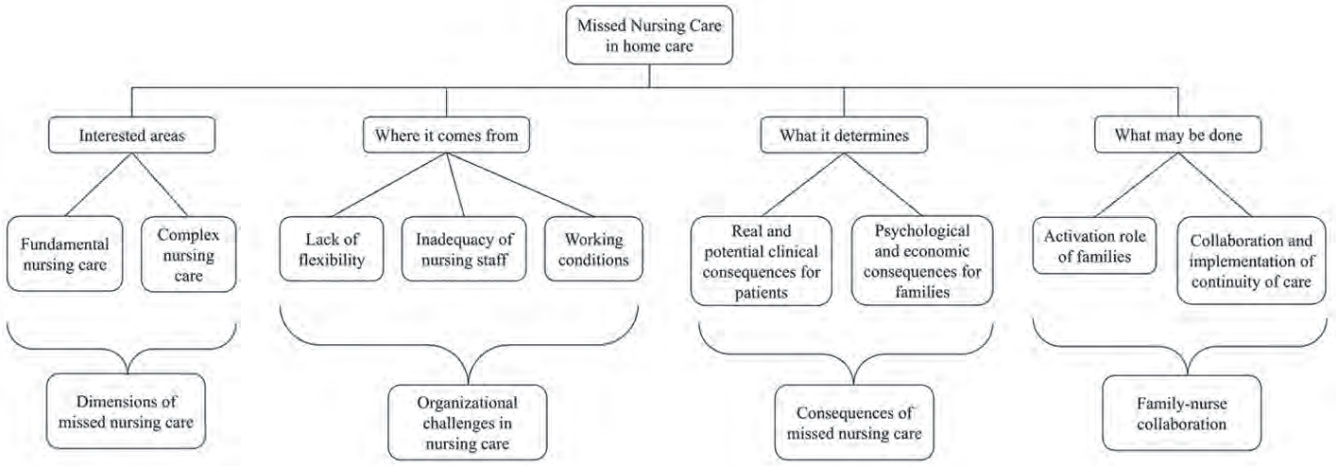

Figure 1. Coding tree for the qualitative analysis.

"I have encountered numerous situations where I was required to address unmet care needs. (…) I remember a case involving a patient enrolled in the integrated home care program. The patient had a bladder catheter placed and required periodic evacuative enemas. (…) I was contacted by the family members outside of regular nursing hours to address a dislodged catheter. (…) In another instance, I was called upon to perform an enema that had been omitted from the patient's care plan". (Interview 12)

"During my five years as a freelance nurse, I have frequently encountered situations where patients' fundamental care needs were not being met. (…) I collaborated with public home care nurses for an oncology patient because colleagues were unable to complete all necessary care interventions, including venipuncture during evening hours. (…) During my visits, I observed a significant complication with the Peripherally Inserted Central Catheter management, characterized by severe thrombophlebitis. This issue was immediately reported to both the integrated home care service and the General Practitioner. Despite the prompt notification, the catheter remained in place, unusable for some days due to delays in obtaining authorization for removal, and the patient did not receive parenteral nutrition". (Interview 1)

"I recall numerous episodes. (...) I remember a patient in the post-surgical period who did not receive adequate information (...) A minimum level of health education was lacking, as the patient and their caregiver did not know who to contact for dressing changes and suture removal. (...) So I was called to provide wound care at home. (...) There is a gap in both the care provided and the education given". (Interview 11)

The second modality through which MNC emerges is represented by complex nursing activities, such as comprehensive assessment and continuous patient management.

"I was once called to assess a patient at home, and I identified malnutrition and dehydration. As a first step, I contacted the General Practitioner to discuss the need for blood tests to identify nutritional deficiencies. (...) Subsequently, I was called to place a nasogastric tube. (...) This intervention could have been avoided by ensuring adequate attention to nutritional status from the onset". (Interview 3)

"Sometimes, patients require services that seem inaccessible to them. (...) This leads families to seek private services. (...) Patient care is not comprehensive; there is a discontinuity between hospital discharge and the initiation of community-based care. (...) Patients often leave the hospital with urinary catheters without knowing how to manage them. (...) I have had to provide not only technical care but also educate the patient and family on how to manage the catheter and the steps to take to obtain home care services". (Interview 5)

Organizational Challenges in Nursing Care

From the experiences of participants, it emerged that the main causes of MNC were generally related to organizational issues within the public home care service. Specifically, the lack of flexibility in service operating hours and the rigid standardization of

interventions led to care gaps, as it is challenging to align these service characteristics with the evolving needs of chronic patients.

"(…) Home care provided by the Public Health Service on Sundays and holidays is greatly reduced, or even absent". (Interview 1)

"(…) The hours [of the Public Health Service] often do not align with the patients' needs". (Interview 9)

"The amount of time dedicated to patients [from the Public Health Service] often isn't sufficient (...) this depends on the Local Health Authority. (...) Today, we can no longer simply reserve a certain time for a specific intervention (...) we should base it on the access itself to determine how much time is needed for each service (...) a professional needs time to perform their job effectively (...) the patient might have other needs besides those for which the professional is paid, which can distract the professional and reduce the efficiency of the service provided". (Interview 3)

Participants highlighted another organizational challenge contributing to MNC, i.e., the insufficient quantity and quality of nursing staff. They believe that the presence of newly graduated or inexperienced nurses, lacking adequate support or specific training, may lead to MNC. Additionally, the chronic shortage of nursing staff across all healthcare settings and service levels is also seen as contributing factor.

"(…) In my experience, the main cause lies in the shortage of personnel and the need to enhance resources in the territory. Unfortunately, in the healthcare sector, attention to territoriality is often overlooked in favour of the hospital". (Interview 7)

"(…) In addition to the shortage of nurses in the public service, another problem arises from the lack of adequate training (...) this shortage not only affects individual nurses but also represents a structural issue that involves cooperatives as well (...) unfortunately, nurses employed by these cooperatives are often professionals who find themselves in this position due to a lack of better opportunities, rather than by choice". (Interview 4)

According to freelance nurses, working conditions also play a significant role in influencing MNC. Currently, the organization and management of home nursing care are entrusted to cooperatives. Participants noted that the operational methods proposed by these cooperatives could contribute to the occurrence of MNC.

"(…) A challenge facing the national healthcare system is the management of public resources. Home care services are typically attributed to cooperatives. These cooperatives hire nurses at much lower salaries than hospitals, resulting in a constant turnover of younger and less experienced nurses, which can compromise the quality of care". (Interview 5)

Furthermore, the lack of professional recognition seems to play a role.

"(…) Within the public service, there is often a lack of adequate incentivization for individual operators, who receive neither proper financial recognition nor tangible support for professional growth (...) I believe it's crucial that employees are motivated and rewarded proportionally to their performance, for example through salary increases and concrete career advancement opportunities (...) it's essential to reward those who demonstrate deserving recognition for their commitment and results". (Interview 6)

Consequences of Missed Nursing Care

From the perspective of freelance nurses, MNC appears to lead to significant consequences for patients and their caregivers clinically, psychologically, and economically.

Clinically, these consequences can be actual or potential, reflecting the risks patients may encounter without intervention from freelance nurses. The timely intervention provided by freelance nurses seeks to address these concrete clinical consequences and mitigate their impact on patient health whenever possible.

"(…) I found myself in a situation where I was asked to help a patient at home. The patient urgently required a urinary catheter (…) The home care nurse responsible for the procedure was unable to arrive promptly as she was engaged in other services, so I placed the urinary catheter. (…) the patient had a distended bladder containing one and a half liters of urine". (Interview 4)

"(…) Thrombophlebitis, resulting from improper vascular access management (…) can have severe implications, including sepsis". (Interview 1)

"(…) In the mechanically ventilated pediatric case I encountered, the consequences could be severe, as a delay in evaluating potential infections in an already compromised patient is more likely to lead to negative outcomes. (…) Intervening at an advanced stage of the situation becomes increasingly difficult". (Interview 7)

Patients and their family members also faced psychological and economic consequences.

"(…) I believe the most serious problem, especially for the patient, is the lack of direct support and a point of reference (...) this leads patient to feel a sense of discomfort and abandonment (...) the presence of a private professional can become an important anchor point (...) furthermore, there are significant consequences for family members. (...) Families are increasingly burdened financially as they must turn to the private sector to receive services that are not available from public services". (Interview 7)

"The family feels lost, enveloped in a sense of abandonment during this phase of their loved one's fragility (...) I could clearly perceive the growing distrust towards the healthcare system". (Interview 1)

Family-Nurse Collaboration

Unmet care needs compel patients' families to quickly develop management skills to address this deficiency. Families play a crucial role in activating freelance nurses in response to MNC.

"Families play a pivotal role in promptly identifying and addressing health issues by taking proactive steps to find the most appropriate professionals. (...) dramatic situations often stem from families' failure to anticipate problems in advance (...) due to complex social circumstances, such as elderly individuals or family members with disabilities, difficulties may compound". (Interview 4)

"(…) In my opinion, families represent a primary and indispensable resource to face missed nursing care at home". (Interview 5)

The role of the family extends beyond just utilizing the services of freelance nurses. A strong bond, akin to a strategic alliance, is formed between nurses and families to address the patient's care needs effectively. The interviewees emphasized the 'collaboration' between families and caregivers. Freelance nurses believe that involving families in the care process and educating them to safely perform certain tasks is crucial for optimal care outcomes. With the family's active support, nurses can ensure continuity of care even in their absence.

"(...) When I enter their homes and demonstrate with competence and professionalism that I am there to help the patient, a bond of trust and respect is created that I cannot find elsewhere, not even in my personal life. These relationships become unique, formed of affection and collaboration, making me perceive working in home care as the most rewarding in the world". (Interview 11)

"The role of the family is essential (...) it is evident that I cannot be present 24 hours a day with them. However, family members can be educated and often are even more proficient than an inexperienced nurse, as they can quickly identify any problems and intervene promptly. They are accustomed to using the ventilator and alarms". (Interview 3)

Discussion and conclusion

To the authors' knowledge, this is the first exploratory study conducted in Europe providing a comprehensive exploration of MNC in home care settings from the perspective of freelance nurses. The on-the-ground experiences of these nurses provide a key new insight: in home care settings, 'not all MNC are truly missed'. The findings reveal that freelance nurses frequently fill gaps in patient care, addressing both fundamental and complex care needs unmet by public services (30). While the intervention of freelance nurses significantly benefits patient health, economic disparities often prevent some patients from accessing these private services, leading to unequal access to care and raising concerns about equity in achieving this global goal (31,32). Consequently, families without sufficient financial resources may face serious health issues. Freelance nurses reported preventing potential negative outcomes such as inappropriate emergency service use, missed medication administration, elimination issues, infections, and nutritional deficiencies. Although this study lacks data on the consequences of inaccessible private services, it is likely that some patients experience these problems, further burdening the national health system.

Another significant aspect highlighted by this study, not previously documented in the literature, is that MNC by the public health system leads families and patients to experience distrust, feelings of abandonment, and dissatisfaction. These psychological implications can interfere with care processes and compliance with therapeutic plans, potentially compromising positive health outcomes (33).

Freelance nurses perceived MNC mainly due to rigid public service schedules based on fixed appointments. Literature indicates that as home

visits increase, the time for each patient decreases, raising the likelihood of MNC (30). Conversely, a well-defined appointment system (19) or longer home visits (30) could help reduce MNC, particularly when time is allocated for both specific tasks and patient education, which freelance nurses often report as lacking in home care (19).

Consistent with the literature, freelance nurses believe unmet care needs are due to inadequate staffing and poor working conditions (5,19,30). Inexperienced nurses, often assigned to home care, may lack skills for high-level assessment and critical thinking, especially in resource-limited settings (34). This inadequacy in experience, knowledge, and skills can significantly impacts patient care. Efficiently navigating transitions in home care requires strategies to support and engage nurses through empowerment and continuous education (35). Implementing organizational strategies to improve nursing capacity with adequate nurse-to-patient ratios and a balanced skill mix is crucial. Enhancing working conditions for home care nurses, who often work for outsourced companies at lower salaries than public services, is also necessary. Lower compensation can lead to perceived poor working conditions, reduced engagement, job satisfaction, and increased intention to leave (30), ultimately affecting patient outcomes.

Finally, this study highlights the critical role of the family when MNC occurs at home. Family members are on the front lines, actively engaging freelance nurses and collaborating to ensure continuity of care, significantly contributing to the patient's well-being. This aligns with the family-centred care model (36), which recognizes the family's central role in the health care journey. Freelance nurses' experiences suggest that staffing constraints, reduced staff experience, high workloads, and time pressures hinder the implementation of this model in home care (37,38). These challenges can lead to negative outcomes such as MNC, and feelings of abandonment and distrust in the healthcare system among patients and their families.

Overall, this study provides critical insights into MNC in home care settings and emphasizes the need for systemic changes. It reveals that not all MNC are truly missed and highlights the crucial role of family involvement. Policy adjustments and further research are essential for improved home care management, nurse engagement, and patient outcomes.

The study's limitations include its qualitative nature and focus on freelance nurses in Italy, which may not be generalizable to other contexts. Although data saturation was reached, the sample size and geographic scope were limited, potentially affecting the diversity of experiences captured. Additionally, participants might not fully recall all instances of MNC. Future research should use larger samples, and mixed method approaches to validate these findings.

The study highlights significant gaps in public nursing care, often filled by freelance nurses. Improving clinical practice requires greater flexibility and continuity in home care services. Public health services should extend operating hours and increase nursing availability during evenings and weekends. Comprehensive training and support for new and less experienced nurses could reduce MNC. Strengthening collaboration between public and private services and actively involving families in patient care are essential.

This study provides a foundation for further research on MNC in home settings, especially from freelance nurses' perspectives. Investigating organizational models like family-centred care and extended home visits could reduce MNC. Additionally, quantitative research is needed to measure MNC prevalence from patients' and families' perspectives. Future studies should explore the impact of socioeconomic factors on access to care and the long-term outcomes of fragmented care.

Riassunto

Dietro le porte chiuse: gli infermieri liberi professionisti e la realtà delle cure infermieristiche perse nell'assistenza domiciliare italiana. Nuove prospettive da uno studio fenomenologico descrittivo

Background. Il termine 'Missed Nursing Care' (MNC) si riferisce a qualsiasi aspetto dell'assistenza infermieristica che non viene erogato, viene erogato parzialmente o viene ritardato. Le MNC hanno conseguenze negative significative, tra cui esiti avversi per i pazienti, rischi per la sicurezza e diminuzione della soddisfazione lavorativa. Sebbene ampiamente studiate negli ospedali, nei contesti di assistenza domiciliare le MNC rimangono poco esplorate, specialmente in Italia. Questo studio si propone di esplorare il fenomeno della MNC nei servizi di assistenza domiciliare italiani, documentando e analizzando le esperienze vissute dagli infermieri freelance, con particolare attenzione alle caratteristiche, ai fattori influenti e alle conseguenze della MNC, così come percepite da questi professionisti sanitari.

Disegno dello studio. È stato condotto uno studio fenomenologico descrittivo.

Metodi. Utilizzando il campionamento a palla di neve 12 infermieri italiani liberi professionisti sono stati reclutati e intervistati da novembre 2022 a febbraio 2023. La raccolta dei dati si è basata su interviste approfondite, trascritte e analizzate utilizzando il framework fenomenologico di Giorgi. Il report dello studio è stato redatto in

base alla checklist COREQ-32 per la ricerca qualitativa.

Risultati. L'analisi tematica ha rivelato quattro temi principali: dimensioni delle MNC, sfide organizzative, conseguenze delle MNC e collaborazione famiglia-infermiere. Gli infermieri liberi professionisti hanno frequentemente soddisfatto bisogni infermieristici di base e complessi non soddisfatti da altri servizi, evidenziando conseguenze cliniche, psicologiche ed economiche significative su pazienti e famiglie. Le criticità organizzative, come gli orari rigidi dei servizi pubblici e il personale insufficiente, sono state identificate come principali cause di MNC. Le famiglie hanno giocato un ruolo cruciale nella gestione dei bisogni insoddisfatti e nella collaborazione con gli infermieri liberi professionisti per garantire la continuità delle cure.

Conclusioni. Questo studio fornisce nuove indicazioni inerenti al fenomeno delle MNC nei contesti di assistenza domiciliare italiano, sottolineando il ruolo critico degli infermieri liberi professionisti nel colmare le lacune assistenziali. I risultati suggeriscono la necessità di cambiamenti sistemici per migliorare la flessibilità, la disponibilità di personale e l'integrazione dei servizi infermieristici pubblici e privati. Ulteriori ricerche, in particolare studi quantitativi, sono essenziali per convalidare questi risultati ed esplorare le implicazioni più ampie per la cura dei pazienti e gli esiti di salute.

References

1. Kalisch BJ, Landstrom GL, Hinshaw AS. Missed nursing care: a concept analysis. J Adv Nurs. 2009 Jul;**65**(7):1509-17. doi: 10.1111/j.1365-2648.2009.05027.x. Epub 2009 May 9. PMID: 19456994.
2. Sochalski J. Is more better?: the relationship between nurse staffing and the quality of nursing care in hospitals. Med Care. 2004 Feb;**42**(2 Suppl):II67-73. doi: 10.1097/01.mlr.0000109127.76128.aa. PMID: 14734944.
3. Ausserhofer D, Zander B, Busse R, Schubert M, De Geest S, Rafferty AM, et al; RN4CAST consortium. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. BMJ Qual Saf.2014 Feb; **23**(2):126-35. doi: 10.1136/bmjqs-2013-002318. Epub 2013 Nov 10. PMID: 24214796.
4. Jones TL, Hamilton P, Murry N. Unfinished nursing care, missed care, and implicitly rationed care: State of the science review. Int J Nurs Stud. 2015 Jun;**52**(6):1121-37. doi: 10.1016/j.ijnurstu.2015.02.012. Epub 2015 Feb 23. PMID: 25794946.
5. Phelan A, McCarty S. Missed Care: Community Nursing in Ireland. Dublin: University College Dublin and the Irish Nurses and Midwives Organisation, 2016. Available from: https://www.justeconomics.co.uk/uploads/reports/Just-Economics-Missed-Care-in-the-Community-Report.pdf [Last accessed: 2024 October 7].
6. Organisation for Economic Co-operation and Development (OECD). Health at a Glance 2021: OECD Indicators. OECD Publishing, Paris. 2022. Available from: https://doi.org/10.1787/ae3016b9-en [Last accessed: 2024 October 7].
7. World Health Organization (WHO). Ageing and health. 2022. Available from: https://www.who.int/news-room/fact-sheets/detail/ageing-and-health [Last accessed: 2024 October 7].
8. World Health Organization (WHO). World health statistics 2022: monitoring health for the SDGs, sustainable development goals. 2022. Available from: https://www.who.int/publications/i/item/9789 [Last accessed: 2024 October 7].
9. Boniol M, Kunjumen T, Nair TS, Siyam A, Campbell J, Diallo K. The global health workforce stock and distribution in 2020 and 2030: a threat to equity and 'universal' health coverage? BMJ Glob Health. 2022 Jun;**7**(6):e009316. doi: 10.1136/bmjgh-2022-009316. PMID: 35760437; PMCID: PMC9237893.
10. Decreto Ministeriale (DM) 23 maggio 2022, n. 77. Regolamento recante la definizione di modelli e standard per lo sviluppo dell'assistenza territoriale nel Servizio sanitario nazionale. GU [Official Gazette of Italian Republic] n.144 del 22-06-2022. Available from: https://www.gazzettaufficiale.it/eli/id/2022/06/22/22G00085/SG [Last accessed: 2024 October 7].
11. Standing Council on Health. National Primary Health Care Strategic Framework. Canberra: Commonwealth of Australia, 2013. Available from: http://www.health.gov.au/internet/main/publishing [Last accessed: 2024 October 7].
12. Ministero della Salute - Agenzia Nazionale per i Servizi Sanitari Regionali. Programma Nazionale Esiti (PNE). Available from: https://pne.agenas.it/home [Last accessed: 2024 August 29].
13. Caponnetto V, Dante A, El Aoufy K, Melis MR, Ottonello G, Napolitano F, et al. Community health services in European literature: A systematic review of their features, outcomes, and nursing contribution to care. Int Nurs Rev. 2024 Jul 29. doi: 10.1111/inr.13033. Epub ahead of print. PMID: 39073363.
14. Recio-Saucedo A, Dall'Ora C, Maruotti A, Ball J, Briggs J, Meredith P, et al. What impact does nursing care left undone have on patient outcomes? Review of the literature. J Clin Nurs. 2018;**27**(11-12):2248-59. doi: 10.1111/jocn.14058. Epub 2017 Oct 16. PMID: 28859254; PMCID: PMC6001747.
15. Nantsupawat A, Poghosyan L, Wichaikhum OA, Kunaviktikul W, Fang Y, Kueakomoldej S, et al. Nurse staffing, missed care, quality of care and adverse events: A cross-sectional study. J Nurs Manag. 2022 Mar;**30**(2):447-54. doi: 10.1111/jonm.13501. Epub 2021 Nov 26. PMID: 34719833; PMCID: PMC9017335.
16. Amrolahi-Mishavan F, Emami-Sigaroudi A, Jafaraghaee F, Shahsavari H, Maroufizadeh S. Factors affecting missed nursing care in hospitals: A scoping review. Health Sciences Review. 2022;**4**:100053. doi: 10.1016/j.hsr.2022.100053.
17. Mainz H, Tei R, Andersen KV, Lisby M, Gregersen M. Prevalence of missed nursing care and its association with work experience: A cross-sectional survey. Int J Nurs Stud Adv. 2024 Mar 27;**6**:100196. doi: 10.1016/j.ijnsa.2024.100196. PMID: 38746807; PMCID: PMC11080405.
18. Papathanasiou I, Tzenetidis V, Tsaras K, Zyga S, Malliarou M. Missed Nursing Care; Prioritizing the Patient's

Needs: An Umbrella Review. Healthcare (Basel). 2024 Jan 16;**12**(2):224. doi: 10.3390/healthcare12020224. PMID: 38255111; PMCID: PMC10815730.
19. Senek M, Robertson S, Ryan T, Sworn K, King R, Wood E, et al. Nursing care left undone in community settings: Results from a UK cross-sectional survey. J Nurs Manag. 2020 Nov;**28**(8):1968-74. doi: 10.1111/jonm.12995.Epub 2020 Mar 30. PMID: 32147888.
20. Matua GA, Van Der Wal DM. Differentiating between descriptive and interpretive phenomenological research approaches. Nurse Res. 2015 Jul;**22**(6):22-7. doi: 10.7748/nr.22.6.22.e1344. PMID: 26168810.
21. Polit DF, Tatano Beck C. Fondamenti di Ricerca infermieristica. Vol.1, Italian 1st ed. Milan: McGraw-Hill Education; 2014.
22. Giorgi A. The theory, practice, and evaluation of the phenomenological method as a qualitative research procedure. J Phenomenol Psychol. 1997;**28**(2):235-60. doi: 10.1163/156916297X00103.
23. Wertz F, Giorgi A. The descriptive phenomenological method in psychology: A modified Husserlian approach. 1st ed. Pittsburgh, PA: Duquesne University Press; 2009.
24. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007 Dec;**19**(6):349-57. doi: 10.1093/intqhc/mzm042. Epub 2007 Sep 14. PMID: 17872937.
25. Patton MQ. Qualitative research & evaluation methods: Integrating theory and practice. 4th ed. Thounsand Oaks, CA: Sage publications; 2014.
26. Benner P. L'eccellenza nella pratica clinica dell'infermiere: l'apprendimento basato sull'esperienza. Italian 1st ed. Milan: McGraw-Hill Education; 2003.
27. Spiegelberg H. Phenomenology through vicarious experience. Doing phenomenology: Essays on and in phenomenology. 1a ed. The Hague: Springer; 1975.
28. Speziale HS, Streubert HJ, Carpenter DR. Qualitative research in nursing: Advancing the humanistic imperative. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.
29. Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. ECTJ. 1981;**29**(2):75-91. https://doi.org/10.1007/BF02766777.
30. Bagnasco A, Alvaro R, Lancia L, Manara DF, Rasero L, Rocco G, et al. Working conditions, missed care and patient experience in home care nursing in Italy: An observational study. Public Health Nurs. 2024 Jul-Aug;**41**(4):709-22. doi: 10.1111/phn.13320. Epub 2024 May 6. PMID: 38708563.
31. Glorioso V, Subramanian SV. Equity in access to health care services in Italy. Health Serv Res. 2014 Jun;**49**(3):950-70. doi: 10.1111/1475-6773.12128. PMID: 24949515; PMCID: PMC4231580.
32. World Health Organization (WHO). Thirteenth general programme of work, 2019–2023: promote health, keep the world safe, serve the vulnerable. 2019. Available from: https://www.who.int/publications/i/item/thirteenth-general-programme-of-work-2019-2023. [Last accessed: 2024 October 7].
33. Birkhäuer J, Gaab J, Kossowsky J, Hasler S, Krummenacher P, Werner C, et al. Trust in the health care professional and health outcome: A meta-analysis. PloS One. 2017 Feb 7;**12**(2):e0170988. doi: 10.1371/journal.pone.0170988. PMID: 28170443; PMCID: PMC5295692.
34. Phelan A, McCarthy S, Adams E. Examining missed care in community nursing: A cross section survey design. J Adv Nurs. 2018 Mar;**74**(3):626-36. doi: 10.1111/jan.13466. Epub 2017 Oct 30. PMID: 28960457.
35. Longhini J, Papastavrou E, Efstathiou G, Andreou P, Stemmer R, Ströhm C, et al. Strategies to prevent missed nursing care: An international qualitative study based upon a positive deviance approach. J Nurs Manag. 2021 Apr;**29**(3):572-83. doi: 10.1111/jonm.13176. Epub 2020 Nov 3. PMID: 33090604.
36. Kokorelias KM, Gignac MA, Naglie G, Cameron JI. Towards a universal model of family centered care: a scoping review. BMC Health Serv Res. 2019 Aug 13;**19**:564. doi: 10.1186/s12913-019-4394-5. PMID: 31409347; PMCID: PMC6693264.
37. Lloyd B, Elkins M, Innes L. Barriers and enablers of patient and family centred care in an Australian acute care hospital: Perspectives of health managers. Patient Exp J. 2018 Nov 6;**5**(3):55-64. doi: 10.35680/2372-0247.1270.
38. Mohammadi N, Seyedfatemi N, Hashemi S. Hindrances to the implementation of family-centered care approach: a grounded theory study. RLH. 2020 Jul 20;**15**(3):170-176. doi: 10.5281/zenodo.4079077.

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Mediterranean diet pattern behaviors and related socio-demographic factors in a sample of nurses: results of an observational study in Italy

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Keywords: Nurses; mediterranean diet; dietary behaviors; nutritional education
Parole chiave: Infermieri; dieta mediterranea; comportamenti alimentari; educazione alimentare

Abstract

Backgound. *Interest in the dietary habits of healthcare professionals, particularly nurses, has increased in recent years. Nurses play a key role in promoting healthy habits among patients, yet often struggle to maintain a balanced diet due to the demanding nature of their profession.*
Study Design. *Cross-sectional.*
Methods. *The sample identified consisted of working students who attend the master's degree course in "Nursing and Midwifery Sciences" at the University of Rome "La Sapienza" and nurses inscribed in several Italian nurses' groups on Facebook, like "Infermiere professionista della salute", "Infermieri attivi", "Infermieri di Roma e Provincia" and "Infermieri Roma". A snowball sampling was used. This observational study was carried out from May to September 2020 through an online platform, and explores the dietary habits of 549 nurses, examining correlations between eating behaviors (Mediterranean Diet Score) and work conditions, such as shift patterns, work hours, and contract types.*
Results. *The Mediterranean Diet Score had a mean value of 7.50 (SD = 1.69). Results show that 90.2% of participants can take short breaks (5-10 minutes) for meals, although stress often affects the quality of these breaks. Nurses with permanent contract ($\beta = 0.098$; $p = 0.021$) and part-time schedules ($\beta = 0.106$; $p = 0.012$) reported healthier eating habits and greater adherence to the Mediterranean diet.*
Conclusions. *The findings highlight the need for improved access to healthy food during long shifts and the implementation of nutritional education programs to support healthier eating habits among nurses.*

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Introduction

Nurses represent the largest group of health professionals. Several studies have shown that this group of workers is often not inclined to follow a healthy diet (1,2). Not following a healthy diet can lead to overweight and obesity and, as a result, to an increase of the risk of disease and a reduction of productivity (2,3). In the last few years, some articles have focused on health professionals working conditions and their health state, especially concerning their eating habits at work. Particularly, these studies analyzed and investigated the cause-effect relationships between these two aspects (4). In addition, there's evidence of several causes of a high stress level linked to poor meal organization (5).

Due to the nature of their profession, nurses should be considered, by the public, as healthy role models (6,7). For this to happen, they must be the first to have satisfactory health conditions (2). On the contrary, it appears that nurses seldom follow a proper diet at work. In fact, during work shifts, their priority is to assist patients' requests in ways and times required by the situation. Shift work is usually associated with irregular meal consumption: lower intake of full meals, lower appetite, lower satisfaction in eating and consumption of high-calorie meals, with a high content of simple carbohydrates (1,8,9). The score of the Mediterranean diet may represent a relevant factor in influencing the quality of employees' diet: it refers to a dietary profile commonly available in the Mediterranean regions (10), in association with adequate and regular physical activity (11). The Mediterranean diet may reduce the physiological effects of stress and promote healthy aging (12). It has also been demonstrated to have significant effects on cardiovascular diseases (13). Problems such as a high risk of overweight and diabetes, which often relates to lower work efficiency, due to continuous absences or leave or even abandonment of premature work, are closely linked to a poor-quality diet (2).

Obesity is widespread among nurses who work for more than 40 hours a week. As a result, nurses' weight gain leads to several issues, such as fatigue and slowdown in the workplace. Among other negative effects, work shifts also negatively affect melatonin production, which influences metabolism and digestion processes (14). Furthermore, there is also a close correlation between their poor health, their bad eating habits and their efficiency in the workplace. In this way, their intrinsic role of assistance and health promoters could be lost and all these aspects could have a negative impact on nurses' lifestyle habits (15).

However, until now, surprisingly, no study has been carried out in Italy on the Mediterranean diet pattern behaviors among nurses, that can be considered the home of the Mediterranean diet. So, our aim was to evaluate what are the dietary behavior (adeherence to Mediterranean Diet) of a sample of nurses and to find socio-demographic factors that have an influence on this behavior.

Methods

The sample identified consisted of working students who attend the master's degree course in "Nursing and Midwifery Sciences" at the University of Rome "La Sapienza" (120 students) and nurses inscribed in several Italian nurses' groups on Facebook, like "Infermiere professionista della salute", "Infermieri attivi", "Infermieri di Roma e Provincia", "Infermieri Roma" (22,440 health professionals). In the first case, all the students answered, while in the second case a snowball sampling was used. We stopped sampling after three waves of remind.

Inclusion conditions were: being a nurse or midwifery; working for a public or private healthcare facility. On the other hand, exclusion criteria were: being retired, working as a freelancer.

They filled in a questionnaire of 50 items to investigate their eating behavior and possible correlations with workflow and shifts (see appendix). This questionnaire was available using a Google form, and its web address was sent to all the master students and posted on the Facebook groups. For all questions mandatory answers were required.

The questionnaire was specifically designed for nurses and it consists of four parts:

- the first part concerns personal data (gender, age, marital status, number of children, level of training, type of contract, area of work and working hours);
- the second part concerns eating habits in the workplace (hunger during the shift, the possibility of taking breaks, free supply of food and water from the company, what food the nurses eat and how many times a week, how much working time affects eating habits) and weekly consumption of the 12 elements that constitutes the Mediterranean diet, using an already validated questionnaire (16);
- the third part concerns safety and characteristics of work (weight loss or gain, episodes of energy loss, eating properly);

- the fourth part concerns the suggestions: in this part, the workers are asked to do the most urgent things to improve working conditions.

The whole process od devopment of the questionnaire was carried out involving two professional dietitians.

The questionnaire was administered from May to September 2020 through an online platform. The participation was anonymous and voluntary. Concerning Ethical considerations, data privacy and confidentiality were assured since no personal data was collected. Moreover, for answering no email address was required. **Informed consent was collected e**nsuring participants know the survey's purpose at the beginning of the Google form.

Statistical Analysis

All analyses were performed using IBM SPSS software for Windows (Statistical Package for the Social Sciences, Version 27). The following steps describe in detail the procedures used to analyse the data:

For quantitative variables, median, minimum and maximum values were calculated to provide an overview of the distribution of the data. For categorical variables, absolute frequencies and percentages were calculated to understand the distribution of sociodemographic and occupational characteristics in the sample.

We calculated the Mediterranean diet (MD) adherence score as follows: for each of the 11 items we applied 1 point for the adherence to MD, and 0 point for non adherence to the MD. Finally we added up the items, with a minimum score of 0 and a maximum of 12, according to the method developed by Mead et al in 2006 (16).

Non-parametric tests were used to examine changes in key variables (such as the Mediterranean diet adherence score). In particular, the Wilcoxon signed ranks test was used to compare any differences in the variables pre- and post-period. The difference between the variables measured before and after (e.g. changes in the Mediterranean diet score) was calculated to obtain the delta variable (Δ), denoted as ΔDiet Score.

For comparisons between two groups, the Mann-Whitney U-test was applied, while for comparisons between more than two groups, the Kruskal-Wallis test was used. These non-parametric tests were chosen to handle possible non-normal distributions of the variables in the sample.

Spearman's rank correlation coefficient was calculated to estimate the direct or indirect relationship between variables such as age, number of children, perceived impact of working hours on eating habits and Mediterranean diet score.

Multivariate linear regression models were developed using the stepwise method with backward elimination of non-significant variables ($p < 0.05$). The dependent variables included the Mediterranean diet score (ΔDiet Score), while the independent variables were demographic and job characteristics such as gender, age, job role, contract type and perceived job stress.

The results of the models were presented using standardised beta coefficients (β) and p-values to indicate the strength and significance of the relationships between variables. Additional regression models were created by stratifying the analysis by gender and age (groups < 52 years and ≥ 52 years) to assess possible modifying effects. The goodness of fit of the different linear regression models was assessed using the coefficient of determination (R^2). A higher R^2 value indicates a better ability of the model to explain the variability in the dependent variable. The significance threshold was set at $p < 0.05$ for all analyses.

Results

This study involved a sample of 549 nurses, of whom 85.8% were women and 14.2% were men. The participants' ages ranged from 22 to 65 years, with a mean age of 38.22 years and a median age of 35 years. In terms of marital status, 56.5% were married or cohabiting, whereas 43.5% were single, separated, divorced, or widowed. Employment data indicated that 17.5% had a self-employed status, VAT registration, or a fixed-term contract, while 82.5% held permanent contracts. Of these, 94.5% worked full-time, whereas 5.5% were part-time employees.

The nurses were classified based on their work area, with 38.2% assigned to medical units, 25.6% to surgical units, 22.4% to emergency/intensive care, and 13.8% to service departments. Regarding shift patterns, 68.7% of participants worked rotating shifts, including night shifts, whereas 31.3% followed a fixed schedule or were on-call.

A significant proportion of participants (29.5%) reported experiencing hunger during their shifts, while 66.1% occasionally felt hungry, and 4.4% did

not experience hunger at work. Meal breaks were reportedly available to 90.2% of the nurses, typically lasting between 5 and 10 minutes. However, 40.1% indicated that their ability to take a break depended on workload and stress levels. In terms of meal choices, 53.4% consumed home-prepared food, while 14.4% relied on ready-made meals. Only 14.2% adhered to specific dietary regimens, including vegetarian, vegan, pescatarian, Mediterranean, lactose-free, gluten-free, ketogenic, low-calorie, and protein-based diets.

Nearly half of the participants (46.6%) reported consuming snacks compulsively in response to stress. Furthermore, 40.1% indicated that their eating habits were significantly influenced by their work schedules, while 33% perceived a high level of influence, 19.3% reported a moderate impact, and only 7.7% considered their dietary choices to be largely unaffected by their work conditions. In addition, 27.5% stated that food offered by patient families influenced their diet, whereas 39.6% reported no impact. Since starting their careers, 41% of nurses experienced weight gain, while 18.9% reported weight loss.

78% can drink at work in any place and 23.3% claim to drink enough. More specifically 70.1% are supplied with bottled drinking water. During the night shift and shifts over 6 hours only 6% of respondents are supplied with food by the company in which they work. 56.1% of the sample has breakfast after the night shift and 15.8% assume more calories before starting the shift. 40.1% of the sample state that eating habits are fully influenced by work shifts, 33% say that it is very influenced, 19.3% think that work affects enough and only 7.7% think that work affects little or no eating habits.

27.5% of nurses state that food brought by parents of patients can affect their eating habits, while 39.6% say that they do not. 41% of the sample say they have had weight gain since working, while 18.9% say they have lost weight since working.

Each participant was asked if and how many times a week he consumed certain foods to investigate adherence to the Mediterranean diet: bread, pasta,

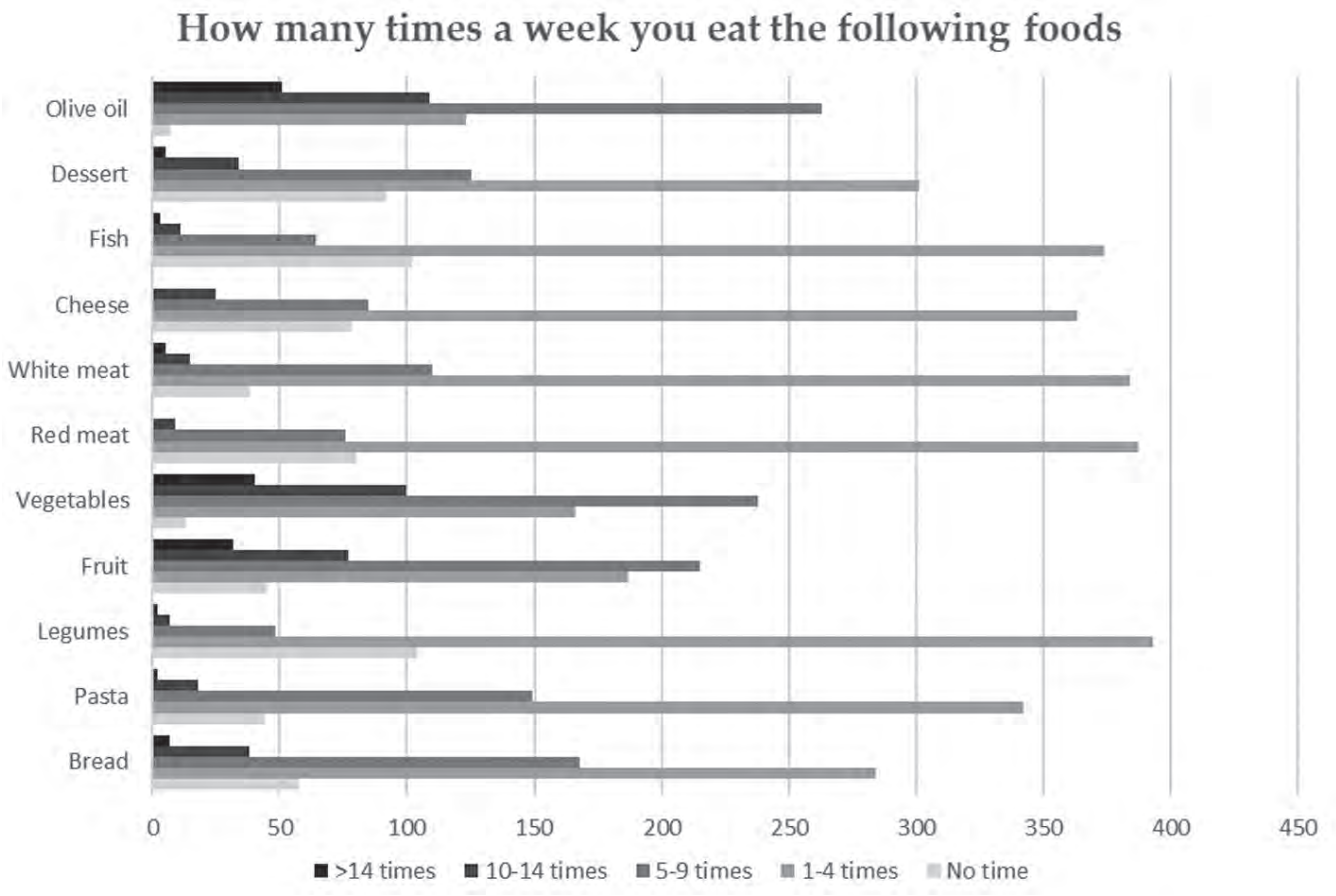

Figure 1 - Number of times the sample usually eats main foods in a week

legumes, fruits, vegetables, red meats, white meats, cheeses, fish, sweets and extra virgin olive oil (Figure 1). The Mediterranean Diet Score had a mean value of 7.50 (SD = 1.69), with a normal distribution observed among the participants.

The study also assessed the willingness of nurses to participate in employer-provided educational programs on stress-related eating disorders. The findings indicated that 15% would attend weekly, 13% would attend twice per month, 30% would attend monthly, 27% would participate up to five times annually, and 14.8% expressed no interest in attending such programs. When asked about their perception of dietary adequacy given their work conditions, responses varied: 5.3% believed they ate appropriately, 17.9% reported eating well, 41% considered their diet moderately adequate, 22% perceived their diet as insufficient, and 13.8% felt they did not eat correctly at all.

Univariate analysis

The Mediterranean diet score data are normally distributed, with a mean of 7.50 (standard deviation = 1.692).

Table 1 shows the means, standard deviations and significance of the variables gender, working environment, educational qualification, time schedule and type of contract.

Bivariate analysis

The correlation contains information about the force and direction of a linear relationship between two variables. The correlation coefficient r may assume values between -1 and 1. Positive values indicate the existence of a positive linear correlation; negative values indicate a negative correlation; 0 indicates no correlation.

The correlations between the variables “age”, “number of children”, “how much do you think your habits are affected by working hours?” and “in your opinion, given how difficult your work is, do you feed properly?” are shown in Table 2.

There is a statistically significant correlation between the score of the Mediterranean diet and the influence that working hours have on the eating habits of nurses.

Moreover, there is a significant correlation between the Mediterranean diet score and “In your opinion, given how hard your job is, do you feed yourself properly?” Those who think they’re eating properly actually do.

Multivariate analysis

The variables included in the Regression Model are gender, age in years, the medical area, Emergency and Services, the type of Contract (determined or indeterminate), the Hours regime (part-time/full-time), “How much do you think your habits are influenced by working hours?”.

In the full model, which is the first step, all these variables are included. We observe in Table 3 the beta standard with relative significance P for each variable considered.

In the following steps, non-significant variables are removed from the model. In the last step, the stepwise model, only the statistically significant variables remain.

Table 1 - Results of the univariate analysis

Variable		Mean (SD)	p
Gender	Male	7.5949 (1.53)	0.580
	Female	7.4809 (1.71)	
Workplace	Internal Medicine wards	7.4673 (1.56)	0.139
	Emergency department	7.6794 (1.82)	
	Surgery wards	7.2143 (1.71)	
	Services	7.6522 (1.73)	
Qualification	Diploma of professional nurse	7.6324 (1.67)	0.477
	University diploma	7.5952 (1.78)	
	Bachelor’s degree	7.4367 (1.68)	
Time schedule	Full time	7.4528 (1.69)	0.010
	Part-time	8.2667 (1.38)	
Contract type	Determined	7.1563 (1.73)	0.030
	Indeterminate	7.5695 (1.67)	

Table 2 - Analysis of the correlation coefficients of the quantitative variables

		Score_ Mediterranean_ Diet	Age in years	Number of children	How much do you think your habits are affected by working hours?	In your opinion, given how hard your job is, do you feed yourself properly?
Score_ Mediterranean_ Diet	Pearson's correlation	1	0.036	0.009	-0.116**	0.200**
	P		*0.406*	*0.841*	*0.007*	*0.001*
Age in years	Pearson's correlation	0.036	1	0.562**	-0.137**	0.091*
	P	*0.406*		*0.001*	*0.001*	*0.032*
Number of children	Pearson's correlation	0009	0.562**	1	-0.004	-0.016
	P	*0.841*	*0.001*		*0.927*	*0.711*
How much do you think your habits are affected by working hours?	Pearson's correlation	-0.116**	-0.137**	-0.004	1	-0.260**
	P	*0.007*	*0.001*	*0.927*		*0.001*
In your opinion, given how hard your job is, do you feed yourself properly?	Pearson's correlation	0.200**	0.091*	-0.016	-0.260**	1
	p	*0.001*	*0.032*	*0.711*	*0.001*	

**. The correlation is significant at level 0.01 (two queues).

*. The correlation is significant at level 0.05 (two queues).

Table 3 - Results of the multivariate analysis

A) Gender: M – W	Full Model	Stepwise Model
	β – standard (p)	β – standard (p)
Female	-0.033 (0.446)	
Age in years	-0.026 (0.596)	
How much do you think your habits are affected by working hours?	-0.115 (0.009)	-0.110 (0.009)
Medical area	0.082 (0.153)	
Emergency	0.115 (0.36)	
Services	0.085 (0.121)	
Time schedule: part_time	0.105 (0.015)	0.106 (0.012)
Contract type: Indeterminate	0.083 (0.073)	0.098 (0.021)

Table 3 shows that the statistically significant variables are:

"How much do you think your habits are affected by working hours?", with a standard beta value of -0.110 and a significance p = 0.009.

Time schedule (part-time), with a standard beta of 0.106 and p = 0.012 and finally the type of contract with a beta standard of 0.083 and p = 0.021.

Following the analysis, it appears that the statistically significant variables are:

- "Considering how tiring your job is, do you feed yourself properly?", awareness of eating properly is associated with the Mediterranean diet score;
- Part-time schedule, if the worker is part-time, he has more time to prepare healthy foods;
- The type of contract: a worker with an open-ended contract has a more correct behavior than someone with other types of contract.

Discussion

The purpose of this paper is to evaluate the relationships between nurses' eating habits, particularly their adherence to the Mediterranean diet, and their role within hospitals, through a 50-item questionnaire structured specifically for nurses.

In our sytudy, the Mediterranean diet score was higher than that found in nurses in Spain (17,18) or Greece (19), Israel (20) and USA (21).

Nurses have been considerd, among the health professionals, those who have the most stressful healthcare activity. However, regular lifestyle, i.e., eating and physical activity, can be helpful to live better (22).

Gender, type of studies and education do not significantly impact nurses' eating habits. In terms of workplace, there are also no major differences between the areas identified except for the emergency area where the situation is slightly better, and this is in line with research carried out in different countries (23).

Significant, however, are the variables related to contract type: workers with permanent contracts eat more correctly than others, as do part-time workers who have more time to prepare healthy foods for themselves.

The greatest difficulties in eating well, as perceived by our sample, relate to the organizational aspects of work. To the question "How much do you think your habits are affected by working hours?" only 7.7% of respondents think that working hours affect their eating habits little or not at all, for all others it affects them to varying degrees and as the perception of the weight of working hours on eating habits increases (40% absolutely yes, 33% very much, 19.3 quite a bit) the Mediterranean Diet score decreases.

In addition, during night shifts and day shifts longer than 6 hours, only 6% of respondents report receiving food from the company and 90.2% report having a break to eat generally of 5-10 minutes, between care needs.

To improve nurses' eating habits, contract stabilization (nurses on permanent contracts eat better) and new recruitment to increase staff strength and decrease workload would be desirable. Companies should also provide full, healthy meals to workers who work shifts longer than 6 hours and ensure adequate breaks for their consumption. The inclusion of healthy snacks in vending machines would also help.

To improve nurses' adherence to the Mediterranean diet, it might also prove useful to organize nutrition education courses in which most respondents were willing to participate (only 14.8% would prefer to engage in other activities).

Our study enrolled a total of 549 participants in the period from May to September 2020, during the Sars-Cov2 pandemic, elements that represent limitations to our study. To confirm and validate our results, future similar studies with a larger sample size, a longer follow-up period, and outside the pandemic emergency context would be desirable.

The administration of the questionnaire studied how a sample of nurses feeds, taking information on personal data (age, title, type of contract and schedule), dietary habits during work and the characteristics and safety of work.

No significant differences were found between males and females, type of studies and post-basic training. As for the field of work, there are no big differences between the four identified areas (medical area, emergency surgical area and services), we see a slightly better situation in the area of emergencies and services. There is a correlation between the type of contract or the part-time or full-time schedule and the Mediterranean diet: it was found that nurses who have a permanent employment contract feed more adequately as well as those working part-time. From these results we can see that all variables that have a significant correlation with the Mediterranean diet are related to work nurses say they have no time.

Taking into consideration the variable "How much do you think your habits are influenced by working hours?" it is seen that this belief decreases the score of the Mediterranean diet.

Also, when asked "How much do you think your habits are affected by working hours?", most workers respond that working hours and shifts affect how they eat. It would be useful to hold or in any case to increase courses in food education for nurses, to provide healthy food on the farm for long shifts, to allow adequate breaks for snacks, try to organize work to reduce stressful interruptions during breaks.

These findings align with previous research indicating that shift work and irregular schedules negatively impact dietary habits among healthcare professionals. Studies suggest that rotating shifts and long working hours lead to poor adherence to healthy diets, including the Mediterranean diet, as they contribute to irregular meal times, increased consumption of processed foods, and decreased intake of fresh produce (24,25). Moreover, stress and workload in hospital settings have been associated with unhealthy eating behaviors, which can ultimately affect the overall well-being and performance of healthcare workers (26). Therefore, interventions such as structured meal breaks and improved availability of nutritious food options at the workplace have been proposed as potential strategies to mitigate these effects (27).

The results of this study are positive. We observe that the nurses of the sample in question feed correctly on average. The eating habits of Italian nurses can be assimilated into the Mediterranean diet, even if they are not explicitly classified as such. However, it is important to acknowledge the strengths and practical implications of these findings. The study highlights the importance of employment stability in promoting healthier eating habits among nurses, suggesting that policies aimed at increasing permanent employment opportunities and reducing excessive workloads could have a positive impact on dietary choices. Additionally, the willingness of most respondents to participate in nutrition education programs indicates a feasible strategy for improving dietary adherence among healthcare professionals.

This paper, though, is not exempt from research limitations, such as the low sample size or potential under-reporting due to possible omissions by nurses. Since the questionnaire was administered online, the researcher could not ensure the accuracy of self-reported data. Additionally, the study was conducted during the peak of the COVID-19 pandemic, a period characterized by extreme workload and psychological stress among healthcare workers, which may have influenced responses and dietary behaviors. These factors introduce potential biases related to self-reporting and external stressors that may not be present in normal working conditions. It would also be interesting to assess how shift work and contract type affect the eating habits of other healthcare professionals. Future research should focus on expanding the sample size and including healthcare workers from different settings and professional categories to obtain a more comprehensive understanding of the relationship between work conditions and dietary habits. Furthermore, longitudinal studies with follow-up assessments could provide more robust evidence on the long-term effects of work schedules on dietary adherence.

Another limitation is that the research was conducted over a short time and during the most acute phase of the coronavirus emergency. Evaluating the long-term effects of these findings through follow-up studies would be valuable. Further research and experimental studies are necessary to validate these results and ensure that healthcare professionals have greater protection in terms of working shifts and contract stability, ultimately improving their dietary habits, well-being, and productivity.

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Riassunto

Aderenza alla dieta mediterranea e relativi fattori socio-demografici in un campione di infermieri: risultati di uno studio osservazionale in Italia

Introduzione. Negli ultimi anni è aumentato l'interesse per le abitudini alimentari degli operatori sanitari, in particolare degli infermieri. Gli infermieri svolgono un ruolo fondamentale nella promozione di abitudini sane tra i pazienti, ma spesso faticano a mantenere una dieta equilibrata a causa della natura impegnativa della loro professione.

Disegno dello studio. Trasversale.

Metodi. Il campione individuato era composto da studenti attivi

che frequentano il corso di laurea magistrale in "Scienze infermieristiche e ostetriche" presso l'Università di Roma "La Sapienza" e infermieri iscritti a diversi gruppi infermieristici italiani su Facebook, come "Infermiere professionista della salute", "Infermieri attivi", "Infermieri di Roma e Provincia" e "Infermieri Roma". È stato utilizzato un campionamento a palla di neve. Questo studio osservazionale è stato condotto da maggio a settembre 2020 attraverso una piattaforma online ed esplora le abitudini alimentari di 549 infermieri, esaminando correlazioni tra comportamenti alimentari e condizioni di lavoro, ed ha esaminato le abitudini alimentari (Punteggio della Dieta Mediterranea) di 549 infermieri, prendendo in considerazione le correlazioni tra i comportamenti alimentari e le condizioni di lavoro, come i turni, le ore di lavoro e i tipi di contratto.

Risultati. Il punteggio della Dieta Mediterranea ha avuto un valore medio di 7,50 (SD = 1,69). I risultati mostrano che il 90,2% dei partecipanti è in grado di fare brevi pause (5-10 minuti) per i pasti, anche se lo stress spesso influisce sulla qualità di queste pause. Gli infermieri con contratti a tempo indeterminato ($\beta = 0{,}098$; $p = 0{,}021$) e orari part-time ($\beta = 0{,}106$; $p = 0{,}012$) hanno riportato abitudini alimentari più sane e una maggiore aderenza alla dieta mediterranea.

Conclusioni. I risultati evidenziano la necessità di migliorare l'accesso a cibi sani durante i turni di lavoro lunghi e di implementare programmi di educazione nutrizionale per sostenere abitudini alimentari più sane tra gli infermieri.

References

1. Seychell J, Reeves S. The effect of shift work on the diet of accident and emergency nurses at the main general hospital in Malta. Proceedings of the Nutrition Society. 2016 Jan 22;**75**(OCE1):E36. doi:10.1017/S0029665115004693.
2. Nejman M, Gotlib J. Impact of nurses' shift work on their nutrition Attitudes. Piel Ęgniarstwo Polskie. 2017;**1**(63). doi: https://doi.org/10.20883/pielpol.2017.1.
3. Beebe D, Chang JJ, Kress K, Mattfeldt-Beman M. Diet quality and sleep quality among day and night shift nurses. J Nurs Manag. 2017 Oct;**25**(7):549-557. doi: 10.1111/jonm.12492. Epub 2017 Jul 11. PMID: 28695685.
4. Yaman GB, Hocaoğlu Ç. Examination of eating and nutritional habits in health care workers during the COVID-19 pandemic. Nutrition. 2023 Jan;**105**:111839. doi: 10.1016/j.nut.2022.111839. Epub 2022 Sep 3. PMID: 36270134; PMCID: PMC9439855.
5. Shrivastava R, Shrivastava P, Pathak T, Nagar J, Jiwane R, Chouhan S, et al. Effect of shift work on dietary habits and occupational stress among nurses in a tertiary care centre: An observational study. J Family Med Prim Care. 2024 Jun;**13**(6):2242-2247. doi: 10.4103/jfmpc.jfmpc_1368_23. Epub 2024 Jun 14. PMID: 39027820; PMCID: PMC11254029.
6. Blake H, Harrison C. Health behaviours and attitudes towards being role models. Br J Nurs 2013 Jan 24-Feb 13;**22**(2): 86-94. doi:10.12968/bjon.2013.22.2.86. PMID: 23587891.
7. Kemppainen T, Tossavainen K, Turunen H. Nurses' roles in health promotion practice: an integrative review. Health Promot Internat.2013 Dec.**28**(4):490-501. doi:10.1093/heapro/das034. Epub 2012 Aug 10. PMID: 22888155.
8. Gadallah M, Hakim SA, Mohsen A, Eldin WS. Association of rotating night shift with lipid profile among nurses in an Egyptian tertiary university hospital. East Mediterr Health J. 2017 Jun 14;**23**(4):295-302. doi: 10.26719/2017.23.4.295. PMID: 28634980.
9. Fradkin L, Raz O, Boaz M. Nurses who work rotating shifts consume more energy, macronutrients and calcium when they work the night shift versus day shift. Chronobiol Int. 2019 Feb;**36**(2):288-295. doi: 10.1080/07420528.2018.1538155. Epub 2018 Nov 5. PMID: 30395719.
10. Capurso C, Massaro M, Scoditti E, Vendemiale G, Capurso A. Review Vascular effects of the Mediterranean diet Part I: Anti-hypertensive and anti-thrombotic effects. Vascul Pharmacol. 2014 Dec;**63**(3):118-26. doi: 10.1016/j.vph.2014.10.001. Epub 2014 Oct 20. PMID: 25446165.
11. Ruggeri S, Rubini G. La nuova Dieta Mediterranea. Gribaudo Editore; 2014.
12. Sofi F, Macchi C, Abbate R, Gensini GF, Casini A. Mediterranean diet and health status: an updated meta-analysis and a proposal for a literature-based aherence score. Public Health Nutr. 2014 Dec;**17**(12):2769-82. doi: 10.1017/S1368980013003169. Epub 2013 Nov 29. PMID: 24476641; PMCID: PMC10282340.
13. Kris-Etherton PEckel RH, Howard BV, St Jeor S, Bazzarre TL; Nutrition Committee Population Science Committee and Clinical Science Committee of the American Heart Association. AHA Science Advisory: Lyon Diet Heart Study. Benefits of a Mediterranean-style, National Cholesterol Education Program/American Heart Association Step I Dietary Pattern on Cardiovascular Disease. Circulation. 2001 Apr 3;**103**(13):1823-5. doi: 10.1161/01.cir.103.13.1823. PMID: 11282918.
14. Chin DL, Nam S, Lee SJ. Occupational factors associated with obesity and leisure-time physical activity among nurses: A cross sectional study. Int J Nurs Stud. 2016 May;**57**:60-9. doi: 10.1016/j.ijnurstu.2016.01.009. Epub 2016 Feb 3. PMID: 27045565; PMCID: PMC4871118.
15. Chiu DT, Parker JE, Wiley CR, Epel ES, Laraia BA, Leung CW, et al. Food insecurity, poor diet, and metabolic measures: The roles of stress and cortisol. Appetite. 2024 Jun 1;197:107294. doi: 10.1016/j.appet.2024.107294. Epub 2024 Mar 11. PMID: 38479471; PMCID: PMC11149909.
16. Mead A, Atkinson G, Albin D, Baic S, Boyd O, Cadigan L, et al; UK Heart Health Group, Thoracic Dietitians Interest Group (Specialist group of the British Dietetic Association). Dietetic guidelines food and nutrition in the secondary prevention of cardiovascular disease – evidence from systematic reviews of randomized controlled trials. J Hum Nutr Diet 2006 Dec; **19**(6): 401-419. doi: 10.1111/j.1365-277X.2006.00726.x. PMID: 17105538.
17. Béjar Prado LM, Mesa Rodríguez P. [Analysis of eating habits among the main health care agents in health promotion (physicians and nurses) of emergency services in times of COVID-19]. Semergen. 2022 Apr;**48**(3):154-162. Spanish. doi: 10.1016/j.semerg.2021.07.001. Epub 2021 Jul 28. PMID: 34419342; PMCID: PMC8316062.

18. Leyva-Vela B, Reche-García C, Hernández-Morante JJ, Martínez-Olcina M, Miralles-Amorós L, Martínez-Rodríguez A. Mediterranean Diet Adherence and Eating Disorders in Spanish Nurses with Shift Patterns: A Cross-Sectional Study. Medicina (Kaunas). 2021 Jun 4;**57**(6):576. doi: 10.3390/medicina57060576. PMID: 34199973; PMCID: PMC8226908.
19. Tountas Y, Manios Y, Dimitrakaki C, Tzavara C. Relationship between basic protective health behaviours and health related quality of life in Greek urban hospital employees. Int J Public Health. 2007;**52**(6):341-7. doi: 10.1007/s00038-007-6079-9. PMID: 18368997.
20. Zaitoon H, Kaly L, Khalil H, Zion N. Balancing Knowledge and Health: A Comparative Analysis of Students and Healthcare Workers Nutrition Related Health Behaviors, a Cross-Sectional Study. Nurs Health Sci. 2024 Dec;**26**(4):e70000. doi: 10.1111/nhs.70000. PMID: 39557424; PMCID: PMC11586509.
21. Wagner M, Grodstein F. Patterns of lifestyle behaviours from mid- through later-life in relation to exceptional episodic memory performance in older women: the Nurses' Health Study. Age Ageing. 2022 May 1;**51**(5):afac102. doi: 10.1093/ageing/afac102. PMID: 35536880; PMCID: PMC9089826.
22. Vitale E. Benefits of Mediterranean and Japanese Diets among Nurses: A Scoping Literature Review. Endocr Metab Immune Disord Drug Targets. 2024;**24**(15):1721-1732. doi: 10.2174/1871530323666230825152320. PMID: 37641993.
23. Kagan I, Ziv A, Rubin C, Murad H, Valinsky L, Asman O, et al. Effect of ethnicity, country of origin and workplace on health behaviors and health perception among nurses: Cross-sectional study. J Nurs Scholarsh. 2022 Sep;**54**(5):535-545. doi: 10.1111/jnu.12759. Epub 2021 Dec 24. PMID: 34951740.
24. Souza RV, Sarmento RA, de Almeida JC, Canuto R. The effect of shift work on eating habits: a systematic review. Scand J Work Environ Health. 2019;**45**(1):7-21. doi: 10.5271/sjweh.3759. Epub 2018 Aug 8. PMID: 30088659.
25. Lowden A, Moreno C, Holmback U, Lennernas M, Tucker P. Eating and shift work - effects on habits, metabolism, and performance. Scand J Work Environ Health. 2010;**36**(2):150-62. doi: 10.5271/sjweh.2898. Epub 2010 Feb 9. PMID: 20143038.
26. Mohajer N, Singh D. Factors enabling community health workers and volunteers to overcome socio-cultural barriers to behaviour change: meta-synthesis using the concept of social capital. Hum Resour Health. 2018 Nov 21;**16**(1):63. doi: 10.1186/s12960-018-0331-7. PMID: 30463573; PMCID: PMC6249815.
27. Geiker NRW, Astrup A, Hjorth MF, Sjödin A, Pijls L, Markus CR. Does stress influence sleep patterns, food intake, weight gain, abdominal obesity and weight loss interventions and vice versa? Obes Rev. 2018 Jan;**19**(1):81-97. doi: 10.1111/obr.12603. Epub 2017 Aug 28. PMID: 28849612.

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APPENDIX

Self-report questionnaire specifically designed for nurses.

Part one: personal data

A) Gender: M – W

B) Age: ___

C) State
1. single/unmarried
2. separate/div.
3. Married/cohabiting
4. Widower

D) Number of children
1. 0
2. 1-2
3. >23.

E) Vocational qualifications
1. diploma of professional nurse
2. Diploma
3. Bachelor's degree

F) Post-basic training
1. specialization
2. Admission to managerial functions
3. Master degree
4. D.A.I, ID, D.D.S.I
5. Master in nursing and midwifery
6. Other degree ----------

G) Employment contract
1. Indefinitely
2. Temporary
3. Co.co.Co
4. Other

H) Working time
1. full-time
2. part-time

I) Clinical working environment
1. medical area
2. surgical area
3. emergency room
4. operating room
5. cancer area
6. outpatient area
7. critical area
8. paediatric area
9. administration

L) How long have you worked for the current company?
1. less than 6 months
2. 6-12 months
3. More than a year

M) Average weekly working hours:
1. <20 hours
2. 20-40 hours
3. >20 hours

N) Typical working hours are:
1. Day shift
2. Afternoon shift
3. Night shift
4. Irregular shift per call
5. Shift rotation

Part two: eating habits at work

A) Are you hungry during working hours?
1. Yes, always
2. Sometimes
3. No

B) Is it possible to take a break to eat or drink during working hours?
1. Yes
2. No

C) If you answered "yes" to the previous answer, how long does it last?
1. -10 minutes
2. 10 minutes
3. Half an hour
4. An hour or more

D) If I could answer the previous question: during the break, where are you allowed to eat?
1. In a fixed place, such as the kitchen or a room for the break
2. Where I want, just don't get dirty
3. Outside the department where you work
4. Outside the facility where you work
5. Other_____

E) Is it possible to drink in the workplace?
1. Yes
2. Only in the break room or kitchen
3. vDepends
4. No

F) If he answered the previous question in the affirmative, do you think you will hydrate enough at work?
1. Yes
2. Sometimes
3. No
4. I can't answer

G) Does the company provide free drinking water in the workplace?
1. Yes
2. No

H) Does the company provide free food and drinks for the night shift or long shift (> 6 hours)?
1. Yes, for both
2. Yes, but only for the night shift
3. Yeah, but only for the long shift
4. No
5. I can't answer

I) On the farm where you work, is there a kitchenette where you can cook or heat food?
1. Yes
2. No

J) Is the room or kitchen where you take a break far from where you work?
1. Yes
2. No

K) If you answered the previous question "yes", how much does it affect the possibility of taking a break?
1. Much
2. Little
3. By no means

L) Do you feel stressed and/or eat fast during your break?
1. Absolutely yes
2. Depends on the workload
3. Sometimes
4. No, I have time to eat stress-free
5. I can't answer

M) How much time do you need to train colleagues in your work, to cover for yourself during the break?
1. A lot, even more reason why it's hard to go on break
2. Depends on the workload
3. Takes little time
4. No, you don't have to
5. I can't answer

N) Is there a food and snack vending machine in your company that is open 24 hours a day?
1. Yes
2. No

O) Does the bar or machines provide healthy food in your company?
1. Yes
2. No
3. I can't answer

P) In your company the bar or machines provide food for vegetarians, vegans, celiacs, diabetics, lactose intolerant?
1. Yes
2. No
3. I can't answer

Q) How many times do you take snacks or high calorie drinks (chocolate bars, sugary drinks, sweets)?
1. once or more a day
2. 2-3 times a week
3. Once a week
4. 1-2 times a month
5. Never

A) Do you consider your work stressful?
1. By no means
2. Somewhat
3. Quite
4. Much
5. Absolutely

S) When you are stressed, is it easier for you to eat a snack?
1. Yes
2. No
3. I can't answer

T) Can you bring food from home to your company?
1. Yes
2. No
3. I can't answer

U) Do you have breakfast immediately when you get home after the night shift?
1. Yes
2. Sometimes
3. No

V) Before starting the shift, do you take more calories, necessary to have enough energy at work, than when you don't have to work?
1. Yes
2. Sometimes
3. No, never

W) If you answered "yes" to the previous question, how many hours before?
1. >2 hours before
2. 2 hours before
3. 1 hour before

X) After eating, before going to work, do you suffer from digestive disorders?
1. Never
2. Few times
3. Sometimes
4. ftentimes
5. Always

Y) Do you follow a particular diet?
1. Yes
2. No

Z) If the answer to the previous question is yes, please indicate:

_____

AA) Indicate how many times a week the following foods are eaten (never, 1-4 times, 5-9 times, 10-14 times, >14 times):
Bread
Pasta
Legumes
Interest bearing
Vegetables
Red meat
White meat
Cheese
Fish
Dessert
Olive oil

AB) How much do you think your habits are affected by working hours?
1. By no means
2. Little
3. Quite
4. Much
5. Absolutely

AC) Do you eat ready-made or home-cooked food more often?
1. Both in the same amount
2. Ready meals
3. Food prepared at home
4. I can't answer

AD) How many times do you eat food offered by relatives of patients at work?
1. Never
2. Sometimes
3. Oftentimes
4. I can't answer

AE) If you answered the previous question in the affirmative: Do you think that having foods offered by relatives often in the workplace can help alter your diet and health?
1. Yes
2. Little
3. No
4. I can't answer

AF) Can colleagues or family members influence your eating habits?
1. Yes
2. Yes, only the colleagues
3. Yes, only family members
4. Sometimes
5. No
6. I can't answer

AG) Does the company where you work organise meetings or consultations on food education?
1. Yes
2. No
3. I can't answer

Part three: safety and characteristics of your work

A) If the company in which the work is carried out were to offer courses in food education or stress-related eating disorders, would it attend them?
1. Yes, once a week
2. Yes, twice a month
3. Yes, once a month
4. Yes, but no more than five times a year
5. No, I prefer other activities

B) Have you taken or lost weight since working?
1. Fattened
2. Lost weight
3. No
4. I can't answer

C) At work, have you ever had episodes of decreased energy, decreased pressure, palpitations or fainting?
1. Yes
2. No

D) If you answered "yes", do you think that with the possibility of taking a break and eating could have been avoided?
1. Yes
2. No
3. I can't answer

E) Considering how hard your work is, do you feed properly?
1. By no means
2. Little
3. Quite
4. Much
5. Absolutely

Part four: suggestions

What do you think are the most urgent things to improve in the company in which you work? (maximum five answers)
1. the comfort of the working environment
2. safety of the working environment
3. professional relationships between colleagues
4. the possibility of eating at work
5. the room for the break or the kitchen closest to where you work
6. free water at work
7. a kitchen where you can heat the food
8. increased attention by food suppliers in the company to the different dietary habits of staff
9. Nutrition and stress management education programs
10. more staff at work
11. less long shifts or less working hours per month (less extra hours)
12. Improving relations with management
13. Improve relationships with nursing management
14. Improve relations with medical staff

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The impact of the Russia-Ukraine conflict on the energy expenditure of public Italian healthcare organizations – A nationwide interrupted series analysis

Elisa Guidotti[1], Marco Di Marco[1]

Keywords: ITS model; sustainability; energy expenditure; hospital; Italian NHS
Parole chiave: Modello ITS; sostenibilità; spesa energetica; ospedali; Servizio Sanitario Italiano (SSN)

Abstract

Background. *Healthcare organizations are complex systems characterized as highly energy intensive structures. Italian healthcare organizations are under increasing pressure due to the external energy dependency, especially following the Russia-Ukranian conflict. Indeed, the ongoing war has generated low energy availability and outbreaking energy costs, thus leading to the aim of the study that is to measure the effect of the Russia-Ukraine war on the energy expenditure of public Italian healthcare organizations.*
Study design & methods. *An Interrupted Times Series analysis was conducted across the period 2017-2022. Details were provided for the nineteen regions and two autonomous provinces. The outcome used was the energy expenditure amount across public healthcare organizations, a Poisson regression model was used. The revenues of public healthcare organizations were included as an offset variable to convert the outcome into a rate and adjust for any potential changes in revenues over time.*
Results. *The model suggested that there is strong evidence of a rise in the energy expenditure following the conflict, with an increase of 56% [relative risk (RR) 1.75] in Italy. All the Italian regions registered a notable increase of the energy expenditure in public healthcare organizations after the conflict, despite inter-regional variability was observed.*
Conclusions. *Several interventions have been carried out to support enterprises and healthcare organizations in managing energy expenditure increases, though National strategies and investments should be set up to guarantee public healthcare organizations' sustainability in the long run.*

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Introduction

Healthcare structures are energy-intensive buildings because of the all-weather operations, sophisticated medical equipment, and well-defined cleaning procedures and environmental parameters (1,2). In Spain, the average annual energy consumption of hospitals reaches 20% of the total consumption in the tertiary sector. Indeed, hospitals are highly complex organizations, comprising a wide range of services and functional units, and their energy expenditure is among the highest among non-residential buildings (3,4). In line, also the Italian healthcare organizations are highly intensive energy consumers (2), and the sector is under increasing pressure due to the Russo-Ukranian conflict. Indeed, since the Second World War, the ongoing Russo-Ukrainian war has been among the most relevant conflicts in Europe, causing multiple economic, geopolitical, and health issues (5). Historically, both Russia and Ukraine have been considered fundamental to global resource markets, particularly for energy. Specifically, Russia is the world's third largest producer and exporter of oil, the second largest producer and the largest exporter of natural gas, and the third largest exporter of coal (thermal and coking). Ukraine has large energy reserves and holds large gas storage and transportation capacity across Europe (6). On the other hand, the European Union is highly energy import dependent, with a natural gas import dependency rate of 84% in 2020 and 83% in 2021 (7,8). Italy registers a high energy import dependency of 94% in 2020 and 93% in 2021, with the highest share of natural gas in the energy mix across Europe. More specifically, Italy in 2021 had Russia as its first gas supply source, followed by Algeria and Azerbaijan (9). The Russo-Ukrainian war thus presents the European Union's dependency on Russian energy with a great challenge. Indeed, the price of natural gas has increased from 20 to 80€/MWh, with peaks to 180€/MWh between February 2021 and 2022, by taking up electricity prices (10). Furthermore, the major Russian governmental energy company has substantially halted exports to Poland, Bulgaria, and Finland, and the transit routes towards Europe through Poland and Ukraine have been progressively turned off (11). The shock brought about by energy availability and price hikes is causing several European governments to be concerned with the sustainability of industrial activities, especially those of highly energy-intensive organizations (12,13). Industry and public administration are among the most important sectors of Italy's economy, with the public administration sector placing third for energy consumption among European countries. In 2020, the Italian public administration sector consumed more than 20 thousand tons of oil equivalent, preceded only by Germany and France (14,15). As part of the Italian public administration, the National Healthcare Servic (NHS) provides assistance to all its citizens and accounts for 7.9% of the Gross Domestic Product (GDP) in 2020 (16). High energy intensity and costs in healthcare facilities, particularly in hospitals, associated with the ongoing war that has generated low energy availability and outbreaking energy costs, make an analysis of the impact of the war on healthcare organizations' energy expenditure crucial for the system's sustainability. This study measures the effect of the Russo-Ukrainian war on the energy expenditure of Italian public healthcare organizations. An Interrupted Times Series analysis has been conducted across the period 2017-2022. Furthermore, details are provided for Italy's nineteen regions and two autonomous provinces (APs).

Study context

The Italian NHS is a decentralized Beveridge system that includes nineteen regions and two APs. The healthcare services have been progressively transferred from the central government to the regions and APs, via subsequential legislative reforms since the early 1990s. Different organizational and funding models developed across regions and APs due to the implemented devolution policies (17). Furthermore, decentralization led to different levels of healthcare expenditure and financial performance (18). The healthcare system is organized and governed at different levels: national, regional, and local (19). The national government plays a stewardship role by defining the essential levels of care to be uniformly granted across Italy and distributing financial resources to the regional governments via general taxation. The regional entities supervise, organize, and deliver primary, secondary, and tertiary healthcare services, as well as preventive and health promotion services. Furthermore, they design and implement regional healthcare plans, coordinate regional strategies, allocate the healthcare budget to the regional organizations, and check that the services provided are appropriate, efficient, and of good quality. The local level is in charge of ensuring the delivery of primary, secondary and tertiary healthcare services via a bunch of healthcare organizations.

The legislative decree 502/1992 established that all Italian public healthcare organizations should change

their accounting systems, moving from traditional financial accounting to accrual accounting, as is the case with private firms. The financial accounting system was regarded as limited because it only measures monetary disbursements incurred (i.e., expenditure) or monetary receipts (i.e., receipts), while accrual accounting also measures costs, returns, and results of daily administrative action (20). Furthermore, legislative decree 118/2011 provided for the harmonization of accounting systems and budget plans, a reform process of public accounting systems aimed at making the balance sheets of healthcare organizations homogeneous and comparable. Energy expenditure must be reported by public healthcare organizations in their income statement (21).

Methods

Data and outcome variable

To measure energy expenditure, we used balance sheets of public healthcare organizations extracted from the Open BDAP website of the Ministry of Economy and Finance (22). The balance sheets record the energy expenditure of each healthcare organization, the regional healthcare system, and the central government. As outcome variable, the quarterly energy expenditure per healthcare organization, region, and country was selected. Balance sheets were analyzed, and the records BA1610 – 'Heating expenditure,' BA1660 - 'Electricity expenditure', and BA1670 - 'Other utilities' were obtained across the nineteen regions and two APs. The record 'Other utilities' was selected since the coding procedures for heating and electricity expenditure are not the same across the regions, and the record 'other utilities' is used as a general heading. Specifically, teaching organizations could report heating costs under the 'Other utilities' heading by specifying the exact coding procedures in dedicated explanatory notes. All the records selected were totaled under the 'Energy expenditure' item. The choice of the outcome variable - 'Energy expenditure' - was made by considering the reference literature (23). The total energy expenditure was extracted from the balance sheets per quarter from January 2017 to December 2022. The total production value for the same period was also extracted to relate energy costs to production, considering that healthcare organizations modified their activities during the pandemic. Indeed, the COVID-19 pandemic forced some drastic changes in clinical and surgical activities (24,25). Planned surgical admissions declined, while emergency activities sharply increased (25). The production value was extracted through the record reference AZ9999 – 'Value of production.' The 'Value of production' consists of several components, mainly state funding, patients' co-payments, and revenue collected through the supply of core activities, hereafter revenues (26). Regional headquarters' energy expenditure was not considered since values were not reported or close to zero.

Statystical analysis

Following Lopez Bernal et al. (23), an interrupted series analysis to examine the trend and level of the public healthcare organizations' energy expenditure before and after the Russo-Ukrainian conflict was carried out. Initial summary statistics and plots were undertaken to gain familiarity with the data. Scatter plots of the time series were realized to identify the underlying trend, seasonal patterns, and outliers. As required for an ITS analysis (27), the chosen segmented regression model and its explanation are reported in (Appendix 1).

As is frequently the case of health data, here the outcome is the energy expenditure amount across public healthcare organizations, without loss of generality, therefore a Poisson regression model was used. Furthermore, the revenues of public healthcare organizations were included as an offset variable to convert the outcome into a rate and adjust for any potential changes in revenue over time (as it occurred due to Covid-19 pandemic). Furthermore, considering that energy expenditure could be affected by seasonal issues, an adjustment for seasonality through a Fourier term was conducted. Furthermore, the model was controlled for over-dispersion and autocorrelation. Indeed, when analyzing real data, it could occur that the variance is greater (over-dispersion phenomenon), and it could cause not-exact standard errors' estimation. Furthermore, when adopting standard regression models, it is often assumed that observations are independent. However, in time series data, it could occur that the assumption is violated due to consecutive observations that are more like one another than those that are further apart. This phenomenon is called autocorrelation (23,27).

All statistical analyses were performed with R free software (28). The analysis was conducted following Lopez Bernal et al., and the results are reported accordingly (23,27).

Results

Italian regional healthcare systems registered an energy consumption expenditure of 11.5 billion euros across the 2017-2022 period. Energy expenditure accounted for around 1.3% of healthcare organizations' revenues, with an increase in 2022 (2.3%).

As with all statistical analyses, initial summary statistics and plots were undertaken to familiarize with the data. A scatterplot of the time series showed that the incidence of energy expenditure over the revenues (from hereby on, energy expenditure rate) was constant across the 2017-2021 period and started to increase between late 2021 and early 2022 (Figure 1). The underlying trend seemed not to show seasonal patterns. Different energy expenditure rate trends were observed across Italian regions, a rate increase was observed between 2021 and 2022 in all the territories (Appendix 2).

Preliminary statistics showed that the mean energy expenditure rate shifted from 1.32 before to 2.29 after the start of the conflict. Table 1 shows basic statics both for the energy expenditure and the rate before and after the conflict.

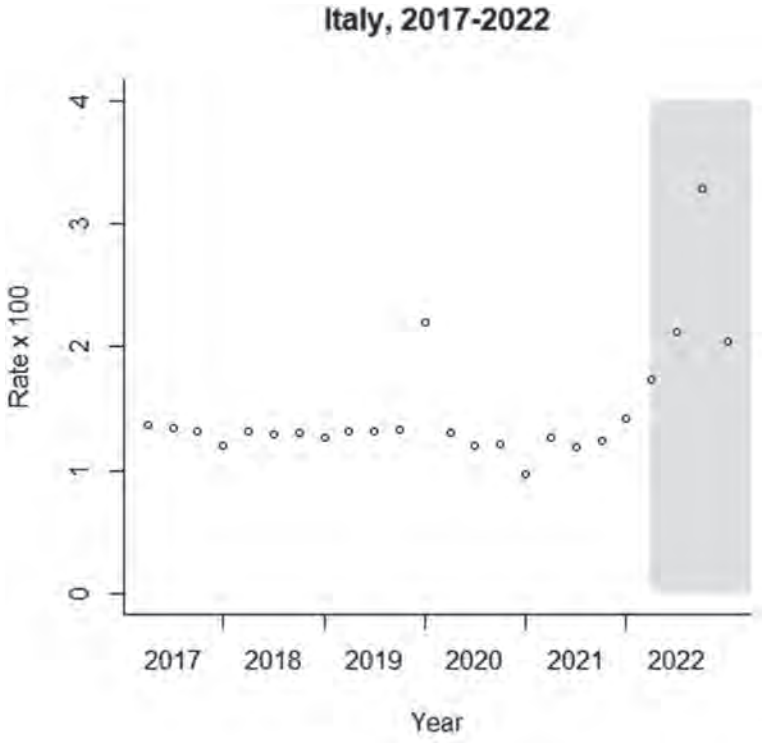

Figure 1 - The figure shows the energy expenditure rate (X100) of Italian public healthcare organizations across the period 2017-2022.

Table 1 - This table shows basic statics both for the energy expenditure and the rate before and after the conflict.

Min.	Lst Qu.	Median	Mean	3rd Qu.	Max
Energy expenditure – No conflict					
345,662,867€	399,568,171€	408,515,610€	425,379,281€	413,861,871€	728,228,887€
Energy expenditure – Conflict					
572,200,000€	679,900,000€	772,200,000€	800,400,000€	892,700,000€	1,085,000,000€
Energy expenditure rate – No conflict					
0.9734	1.2406	1.3068	1.3225	1.3269	2.2034
Energy expenditure rate – Conflict					
1.736	1.966	2.080	2.294	2.409	3.281

(Segue Tab. 1)

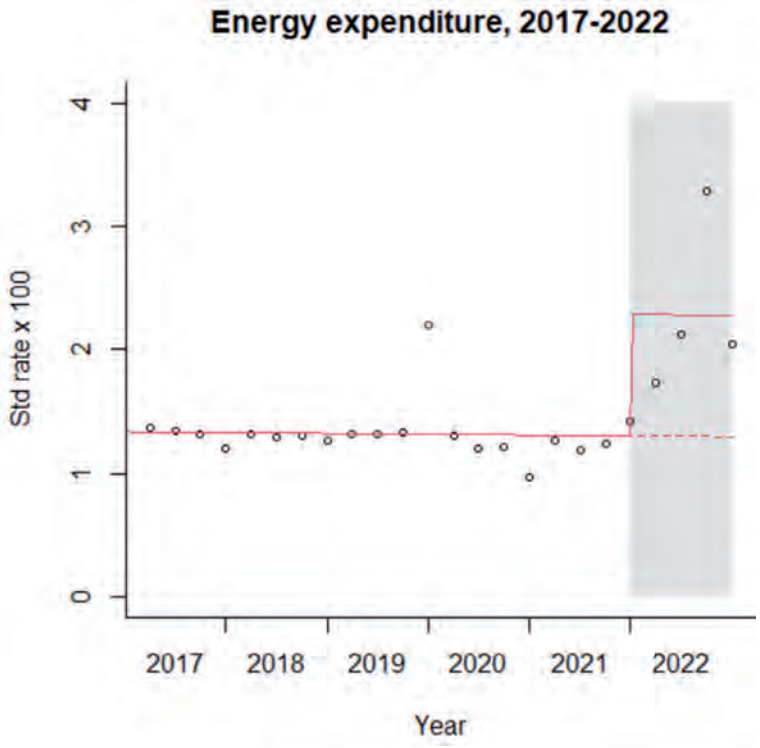

Figure 2 - This figure displays the pre-intervention trend of quarterly energy expenditure rate (continuous line), and the counterfactual scenario (dashed line) for the Italian public healthcare organizations.

Poisson regression model suggested that there is strong evidence of a rise in energy expenditure following the conflict, with an increase of 56% [relative risk (RR) 1.75]. Figure 2 displays the pre-intervention trend of quarterly energy expenditure rate (continuous line), and the counterfactual scenario (dashed line). Given that most of the points lie above the counterfactual line, there is a visual suggestion of an increase in the energy expenditure in the post-intervention period, which is compatible with a possible negative impact of the conflict.

The Poisson regression model revealed energy expenditure in public healthcare organizations decreased slowly by 0.1% per quarter in the baseline (pre-conflict). Differences were observed across regions, some registered an increasing baseline trend (Abruzzo, 1.3%; Basilicata, 2.4%; A.P Bolzano, 1.5%; Campania, 0.2%; Lazio, 0.2%; Liguria, 2%; Molise, 3%; Sardegna, 2%; Sicilia, 1%; Umbria; 1%). Other regions revealed a slightly decreasing baseline trend (Calabria, -1%; Emilia-Romagna, -1.7%; Friuli-Venezia Giulia, -2%; Marche, -0.1%; Piemonte, -1%; Puglia, -0.1%; Toscana, -1.6%; A.P Trento, -1%; Valle D'aosta, -0.8% and Veneto, -0.2%). All the Italian regions registered an increase in energy expenditure after the conflict, however the increments ranged from 94% of Emilia-Romagna [relative risk (RR) 2.57; 95% confidence interval (CI) 2.570-2.571; P < 0. 001)] to lower increase levels, 50% of Campania [relative risk (RR) 1.66; 95% confidence interval (CI) 1.656-1.657; P < 0. 001)]. Regression analysis and counterfactual graphs for all the regions are available in (Appendix 3).

The controls revealed no over-dispersion and autocorrelation. Specifically, for the over-dispersion, in the analysis this widens the 95% confidence interval marginally to 1.521-2.676, yet there is still very strong evidence of an effect (P < 0.001). The residual plot showed no evidence of autocorrelation.

Further checks on seasonality suggested the association was largely unaffected [relative risk (RR) 2.140; 95% confidence interval (CI) 1.670-2.740; P < 0. 001)]. Figure 3 shows the analysis after adjustment for seasonality through a Fourier term.

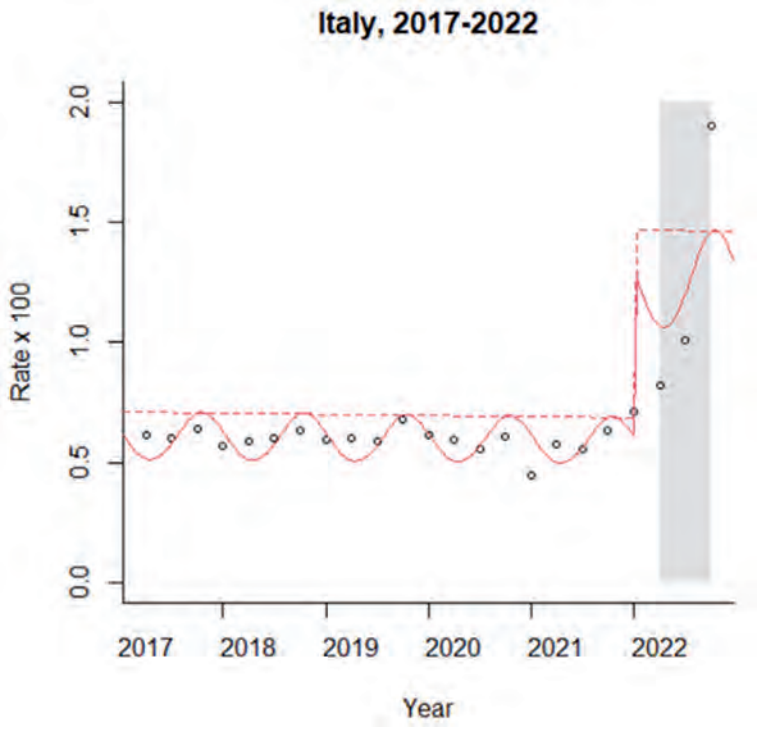

Figure 3 - This figure displays the analysis after adjustment for seasonality through a Fourier term.

Discussion

The Italian healthcare system is increasingly under pressure due to the increasingly elderly population, the high prevalence of chronic diseases, together with the COVID-19 pandemic, has required extraordinary healthcare efforts (29). The Russo-Ukrainian conflict has emerged as another element that could affect the sustainability of international health systems, due to the increase in energy costs and since healthcare organizations are energy-intensive structures (3,4). Therefore, the purpose of this study was to conduct preliminary analyses to measure the effect of the Russo-Ukrainian war on the energy expenditure of public Italian healthcare organizations. Summary statistics and plots revealed that the energy expenditure of public Italian healthcare organizations was stable across the 2017-2021 period, with most regions registering a slightly decreasing pre-conflict trend. Furthermore, Energy expenditure accounted for 1% of healthcare organizations' revenues before the conflict, in line with previous literature that revealed that personnel accounts for most of the total costs, jointly with good and services expenditure (30). Trend plots revealed that the energy expenditure started to increase at the end of 2021, thus showing an anticipation to the beginning of the conflict. This behavior could be referred to as the 'anticipated inflation' phenomenon (31). People's anticipations about the inflation rate matter because actual inflation depends, in part, on what it is expected to be; anticipations influence product and services' price-setting, wage bargaining and spending/saving decisions. All Italian regions registered a notable increase of the energy expenditure rate in public healthcare organizations after the conflict, although inter-regional variability was observed. Variability across regions has been historically observed when observing healthcare systems phenomena, being probably the natural result of a decentralized system (18,32). Regional differences could also be due to the healthcare organization structural characteristics and their geographical location. The energy expenditure of a healthcare organization could be influenced by the healthcare organization's structural characteristics, or the organizational model adopted. Latha et al.(33) highlighted that the layout of a building may have a relevant influence on the environmental energy performance. The 2021 National Recovery and Resilience Plan (PNRR) moved towards this direction, with an investment of over 1.6 billion euros dedicated to adapting old healthcare organization structures to current regulations on construction in seismic areas

and energy saving. The energy expenditure increase hit most of the economic sectors. According to data from ARERA, the Regulatory Agency for Energy, Networks and Environment, across the1 April 2021 - 31 March 2022 period, an increase of about 68% was registered for family consumption, reaching an increase in expenditure of about 823 euros for a typical family with an active supply in the protected market (34). The Italian government has introduced several decrees to support families and enterprises, through several instruments as for example tax credit increases especially for high consuming factories. As for families and enterprises, healthcare organization directions require dedicated funds to face cost increases. Indeed, the Government has provided specific temporary funds for the energetic costs increase (35), however structural financial manoeuvres are needed to guarantee healthcare organizations' long term sustainability. The topic of healthcare organization sustainability has largely been discussed in Italy, and several policies have been implemented by the central government to avoid default risk. Although regional governments are in charge of the financial-economic equilibrium of healthcare organizations, several interventions in the last 15 years have been carried out by central authorities to ensure the provision of essential healthcare services, as well as financial and economic stability, the so-called 'Recovery plans' (30). The adoption of recovery plans turned out to be successful in reducing costs, however with no gains in efficiency estimated. The cost reduction resulted in reduced hospitalizations and in some cases even in a mortality increase (36). Energy expenditure increases should be analyzed and monitored by the authorities to avoid undermining the sustainability of the public health system and possibly having to reduce the health services offered as cost-cutting results. Indeed, Tsagkaris et al. highlighted that electricity shortages can lead to unfortunate incidents and hazardous behaviors. For example, electricity cuts could lead to cuts in operating rooms availability, thus increasing waiting lists and limit the continuity of interventions. Electricity cutting could also influence healthcare professionals that are extremely exposed to power blackouts. Indeed, the unavailability of electricity power can cause healthcare workers stress, both physical and psychological, as they are required to manage critically ill patients without the fundamental electronic equipment (37). This dynamic is especially harmful in the post-pandemic era since healthcare personnel have already experienced stressful situations, and worldwide healthcare systems have been exposed to high economic pressures. Further studies should be conducted to analyze the phenomenon in other European countries. Indeed, the uptake of pan-European actions could contrast the healthcare organizations' energy expenditure' increase and guarantee proper universal healthcare assistance.This study presents several limitations. The foremost of which concerns the availability of data per quarter. Lopez Bernal et al. (23) presented monthly datasets for the evaluation of public healthcare interventions. Indeed, Zhang et al. (38) conducted simulations and realized that studies with few time points or with small, expected effect sizes should be interpreted with caution since they may be underpowered. The powers' model increases with the number of time points, even though a high number of points could also not be preferable in the case of historical paths that have significantly changed substantially as this could not give a clear picture of the existent underlying trends. Quarterly data could also affect seasonality since monthly changes could not be observed. However, several ITS analysis on healthcare dataset were successfully conducted on quarterly data (39). Administrative data (also known as claims data or secondary data) are data collected for non-research purposes (often for billing purposes), thus they may be missing particular data points or may not be perfectly up to date. Indeed, the Italian Ministry of Health and the Ministry of Economy and Finances requires continous data revisions and updates. Furthermore, this analysis considered only public healthcare organizations, and not private ones that play an increasingly important role in the Italian healthcare sector.

The study was carried out as of potential interest by considering the pandemic scenario, different research could be of interests and other results could occur in a different time period. Studies considering all healthcare organizations could enhance the evaluation of the impact of the conflict on the energy expenditure and even identify differences considering their structure and organization.

Conclusions

This analysis showed the conflict generated a significant energy expenditure increase in public healthcare organizations across all the Italian regions, reporting a preliminary worrying trend for the sustainability of public healthcare organizations. While such an increase could be considered not that

relevant, since energy expenditure accounts for a small part of the revenues, it is important given the historical Italian healthcare organizations' sustainability issues. These preliminary findings suggest most healthcare organizations in Italy could not be able to offer essential levels of care due to cost-cutting as occurred in the past. Several interventions have been carried out to support families and enterprises in managing energy expenditure increases, thus revealing potential actions that have been transferred also to the healthcare sector. As broader interventions, Italy should start thinking in investing in new energy sources that would allow the country to be less energy dependent on other countries and to external phenomena such as conflict. Furthermore, national strategies and investments should be set-up to realize energy-efficient healthcare organizations, together with healthcare prevention actions. Indeed, co-benefit policies, that provide for the convergence of climate change mitigation and disease prevention policies, have been shown to lead to major economic benefits.

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Riassunto

L'impatto del conflitto Russo-Ucraino sulla spesa energetica delle aziende sanitarie pubbliche italiane – Un'analisi ITS (Interrupt time-serie)

Introduzione. Le organizzazioni sanitarie sono sistemi complessi caratterizzati da strutture ad alta intensità energetica. Le organizzazioni sanitarie italiane sono sempre più sotto pressione a causa della dipendenza energetica esterna, soprattutto a seguito del conflitto russo-ucraino. La guerra in corso, infatti, ha generato una bassa disponibilità di energia e un'impennata dei costi energetici, portando così all'obiettivo dello studio che è quello di misurare l'effetto della guerra sulla spesa energetica delle aziende sanitarie pubbliche italiane.

Disegno dello studio e metodi. Nel periodo 2017-2022 è stata condotta un'analisi delle serie temporali interrotte. L analisi è stata condotta per le diciannove regioni e le due province autonome italiane. L'outcome utilizzato è stato l'importo della spesa energetica delle le organizzazioni sanitarie pubbliche, congiuntamente a un modello di regressione di Poisson. I ricavi delle organizzazioni sanitarie pubbliche sono stati inclusi come variabile offset per convertire il risultato in un tasso e adeguarsi a eventuali variazioni dei ricavi nel tempo.

Risultati. Il modello ha messo in evidenza un aumento della spesa energetica delle organizzazioni sanitarie pubbliche a seguito del conflitto, con un aumento del 56% [rischio relativo (RR) 1,75] in Italia. Tutte le regioni italiane hanno registrato un notevole incremento del costo energetico, nonostante sia stata osservata una variabilità interregionale.

Conclusioni. Diversi interventi sono stati realizzati per supportare le imprese e le organizzazioni sanitarie nella gestione degli aumenti della spesa energetica, anche se dovrebbero essere messe in atto strategie e investimenti nazionali per garantire la sostenibilità delle organizzazioni sanitarie pubbliche nel lungo periodo.

References

1. Shen C, Zhao K, Ge J, Zhou Q. Analysis of Building Energy Consumption in a Hospital in the Hot Summer and Cold Winter Area. Energy Procedia. 2019 Feb;**158**:3735-40. doi: https://doi.org/10.1016/j.egypro.2019.01.883.
2. Yuan F, Yao R, Sadrizadeh S, Li B, Cao G, Zhang S, et al. Thermal comfort in hospital buildings – A literature review. J Building Engineering. 2022 Jan;**45**:103463. doi: https://doi.org/10.1016/j.jobe.2021.103463.
3. González González A, García-Sanz-Calcedo J, Salgado DR. A quantitative analysis of final energy consumption in hospitals in Spain. Sustain Cities Soc. 2018 Jan 1;**36**:169-75. doi: 10.1016/j.scs.2017.10.029.
4. Papadopoulos AM. Energy Efficiency in Hospitals: Historical Development, Trends and Perspectives. In: Energy Performance of Buildings. Cham: Springer International Publishing; 2016: 217-33.
5. Rawtani D, Gupta G, Khatri N, Rao PK, Hussain CM. Environmental damages due to war in Ukraine: A perspective. Sci Total Environ. 2022 Dec;**850**:157932. doi: 10.1016/j.scitotenv.2022.157932. Epub 2022 Aug 9. PMID: 35952889.
6. Benton TG, Froggatt A, Wellesley L, Grafham O, King R, Morisetti N, et al. The Ukraine war and threats to food and energy security Cascading risks from rising prices and supply disruptions. London: Chatham House; 2022. ISBN: 978 1 78413 522 5. doi: 10.55317/9781784135225. Available from: https://www.chathamhouse.org/2022/04/ukraine-war-and-threats-food-and-energy-security [Last accessed: 2025 Jan 10].
7. Eurostat. EU natural gas import dependency down to 83% in 2021 [Internet]. 2022. Available from: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220419-1 [Last accessed: 2025 Jan 10].
8. Prohorovs A. Russia's War in Ukraine: Consequences for European Countries' Businesses and Economies. J Risk Financial Manag. 2022 Jul 2;**15**(7):295. doi: 10.3390/jrfm15070295.
9. Eurostat. Energy statistics database [Internet]. Available from: https://ec.europa.eu/eurostat/web/energy [Last accessed: 2025 Jan 10].
10. Heather P. The role of the traded gas hubs. In: A Series of Unfortunate Events - Explaining European Gas Prices in 2021. [Internet]. 2022. Available from: https://a9w7k6q9.stackpathcdn.com/wpcms/wp-content/uploads/2022/03/Insight-111-Explaining-European-gas-prices-in-2021-the-

role-of-the-traded-gas-hubs.pdf [Last accessed: 2025 Jan 10].
11. Hudec M. Gazprom Did Not Reserve Gas Transit Capacity for June Via Slovakia, Poland [Internet]. Euractiv; 2022. Available from: https://www.euractiv.com/section/energy-environment/news/gazprom-did-not-reserve-gas-transit-capacity-for-june-via-slovakia-poland/ [Last accessed: 2025 Jan 10].
12. Osička J, Černoch F. European energy politics after Ukraine: The road ahead. Energy Res Soc Sci. 2022 Sep;**91**:102757. doi: 10.1016/j.erss.2022.102757.
13. Ferriani F, Gazzani A. The impact of the war in Ukraine on energy prices: consequences for firms' financial performance [Internet]. 2022. Available from: https://ssrn.com/abstract=4216406 [Last accessed: 2025 Jan 10].
14. Eurostat. Final energy consumption by sector. 2024.
15. European Union. Country profiles [Internet]. Available from: https://european-union.europa.eu/principles-countries-history/country-profiles/italy_en [Last accessed: 2025 Jan 10].
16. Ministero della Salute, Italy. Servizio Sanitario Nazionale: i LEA [Internet]. 2022. Available from: https://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?id=5073&area=Lea&menu=vuoto [Last accessed: 2025 Jan 10].
17. Tediosi F, Gabriele S, Longo F. Governing decentralization in health care under tough budget constraint: What can we learn from the Italian experience? Health Policy (New York). 2009 May;**90**(2-3):303-12. doi: 10.1016/j.healthpol.2008.10.012. Epub 2008 Dec 5. PMID: 19058869.
18. de Rosis S, Guidotti E, Zuccarino S, Venturi G, Ferré F. Waiting time information in the Italian NHS: A citizen perspective. Health Policy (New York). 2020 Aug;**124**(8):796-804. doi: 10.1016/j.healthpol.2020.05.012. Epub 2020 May 28. PMID: 32624247.
19. Ferre F, de Belvis AG iulio, Valerio L, Longhi S, Lazzari A, Fattore G, et al. Italy: health system review. Health Syst Transit. 2014;**16**(4):1-168. PMID: 25471543.
20. Boccaccio A, Cinquini L, Nuti S, Vainieri M. La potenzialità della contabilità economico-patrimoniale per il confronto di performance tra Aziende Sanitarie: l'esperienza della Regione Toscana. In: Barretta A, Vagnoni E, eds. Il benchmarking in ambito sanitario. CEDAM; 2005.
21. Regione Piemonte. L'armonizzazione dei sistemi contabili e degli schemi di bilancio [Internet]. Available from: https://www.regione.piemonte.it/web/amministrazione/finanza-programmazione-statistica/bilancio/larmonizzazione-dei-sistemi-contabili-degli-schemi-bilancio [Last accessed: 2025 Jan 10].
22. Banca dati Amministrazioni Pubbliche (Open BDAP) [Internet]. 2024. Available from: https://openbdap.rg.mef.gov.it/ [Last accessed: 2025 Jan 10].
23. Lopez Bernal J, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial. Int J Epidemiol. 2017 Feb 1;**46**(1):348-355. doi: 10.1093/ije/dyw098. PMID: 27283160; PMCID: PMC5407170.
24. Mariani NM, Pisani Ceretti A, Fedele V, Barabino M, Nicastro V, Giovenzana M, et al. Surgical Strategy During the COVID-19 Pandemic in a University Metropolitan Hospital in Milan, Italy. World J Surg. 2020 Aug 16;**44**(8):2471-6. doi: 10.1007/s00268-020-05595-y. PMID: 32418029; PMCID: PMC7229874.
25. Zagra L, Faraldi M, Pregliasco F, Vinci A, Lombardi G, Ottaiano I, et al. Changes of clinical activities in an orthopaedic institute in North Italy during the spread of COVID-19 pandemic: a seven-week observational analysis. Int Orthop. 2020 Aug 24;**44**(8):1591-8. doi: 10.1007/s00264-020-04590-1. Epub 2020 May 24. PMID: 32449043; PMCID: PMC7245996.
26. Cantù Elena, Anessi Pessina Eugenio, Persiani Nicolò. Armonizzazione contabile e revisione dei bilanci nelle aziende sanitarie pubbliche. L'aziendalizzazione della sanità in Italia. In: Cantù E, Ed. L'Aziendalizzazione della Sanità in Italia. Rapporto OASI; 2011: 469-94.
27. Lopez Bernal J, Soumerai S, Gasparrini A. A methodological framework for model selection in interrupted time series studies. J Clin Epidemiol. 2018 Nov;**103**:82-91. doi: 10.1016/j.jclinepi.2018.05.026. Epub 2018 Jun 6. PMID: 29885427.
28. The R Project for Statistical Computing [Internet]. 2024. Available from: https://www.r-project.org/ [Last accessed: 2025 Jan 10].
29. Ricciardi W, Tarricone R. The evolution of the Italian National Health Service. Lancet. 2021 Dec;**398**(10317):2193-206. doi: 10.1016/S0140-6736(21)01733-5. Epub 2021 Oct 22. PMID: 34695372.
30. CERGAS-Bocconi University, Eds. Osservatorio sulle Aziende e sul Sistema sanitario Italiano. Rapporto OASI 2023 [Internet]. Milano: Egea; 2023. ISBN 978-88-238-4763-7. Available from: https://cergas.unibocconi.eu/sites/default/files/media/attach/Rapporto_OASI_2023_0.pdf?VersionId=o1QXm9qPi7HP3iz6bXzNpKBUK_CV_hpi [Last accessed: 2025 Jan 10].
31. European Central Bank. Inflation expectations and the strategy review [Internet]. Available from: https://www.ecb.europa.eu/home/search/review/html/inflation-expectations.en.html [Last accessed: 2025 Jan 10].
32. Pirrotta L, Guidotti E, Tramontani C, Bignardelli E, Venturi G, De Rosis S. COVID-19 vaccinations: An overview of the Italian national health system's online communication from a citizen perspective. Health Policy (New York). 2022 Oct;**126**(10):970-9. doi: 10.1016/j.healthpol.2022.08.001. Epub 2022 Aug 4. PMID: 35987784; PMCID: PMC9349029.
33. Latha H, Patil S, Kini PG. Influence of architectural space layout and building perimeter on the energy performance of buildings: A systematic literature review. Int J Energy Environ Eng. 2022 Sep 8;**14**:431-74. doi: 10.1007/s40095-022-00522-4.
34. Autorità di Regolazione per Energia Reti e Ambiente (ARERA). Arera per il consumatore [Internet]. 2024. Available from: https://www.arera.it/it/index.htm# [Last accessed: 2025 Jan 1].

35. il Sole 24h Sanità. Fiaso e Aiop: un contributo straordinario agli ospedali per fronteggiare i rincari dell'energia [Internet]. 2022 Aug 30. Available from: sanita24.ilsole24ore.com/art/imprese-e-mercato/2022-08-30/cittadini-aiop-il-caro-energia-mette-rischio-diritto-salute-cittadini-121828.php?uuid=AEqbAWwB [Last accessed: 2025 Jan 10].
36. Depalo D. The side effects on health of a recovery plan in Italy: A nonparametric bounding approach. Reg Sci Urban Econ. 2019 Sep 1;**78**:103466. doi: 10.1016/j.regsciurbeco.2019.103466.
37. Tsagkaris C, Laubsher L, Matiashova L, Lin L, Isayeva A. The impact of energy shortages on health and healthcare in Europe. Health Sci Rep. 2023 Jan 26;**6**(2): e1075. doi: 10.1002/hsr2.1075. PMID: 36721397; PMCID: PMC9880148.
38. Zhang F, Wagner AK, Ross-Degnan D. Simulation-based power calculation for designing interrupted time series analyses of health policy interventions. J Clin Epidemiol. 2011 Nov;**64**(11):1252-61. doi: 10.1016/j.jclinepi.2011.02.007. PMID: 21640554.
39. Lopez Bernal JA, Lu CY, Gasparrini A, Cummins S, Wharham JF, Soumerai SB. Association between the 2012 Health and Social Care Act and specialist visits and hospitalisations in England: A controlled interrupted time series analysis. PLoS Med. 2017 Nov 14;**14**(11):e1002427. doi: 10.1371/journal.pmed.1002427. Erratum in: PLoS Med. 2018 Feb 26;15(2):e1002527. doi: 10.1371/journal.pmed.1002527. PMID: 29135978; PMCID: PMC5685471.

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Appendixes

Appendix 1

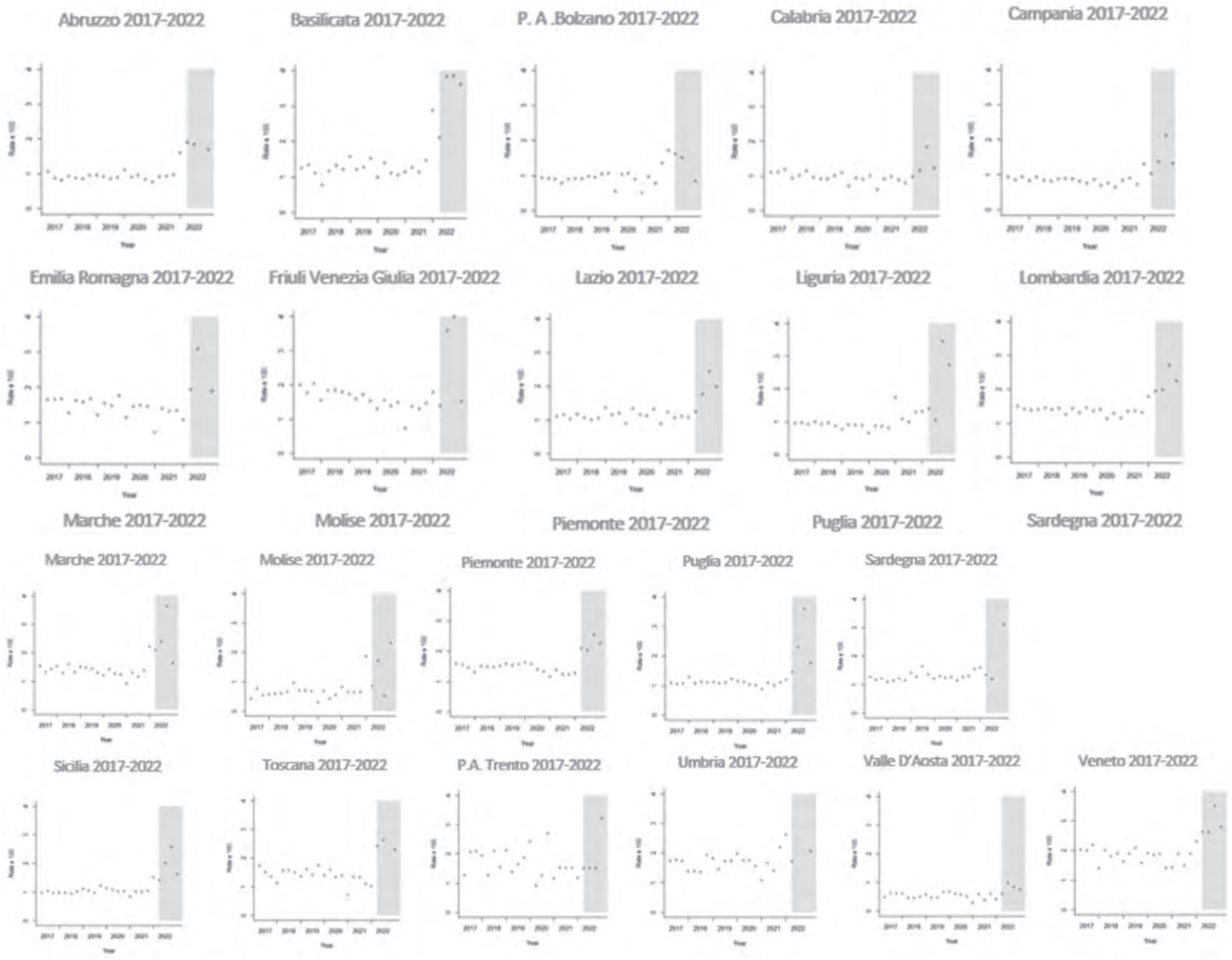
The chosen segmented regression model is:

$$Y_t = \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 TX_t$$

where Y_t is the energy expenditure in quarter t and time is a continuous variable reflecting time from the start of the observation period in quarters. Intervention (hereafter=conflict) takes value 0 before the conflict and 1 after the conflict started, and time after intervention is a continuous variable indicating time after the reform in quarters. β_0 is the baseline level at T=0, β_1 can be regarded as the change in outcome due to a time unit increase (representing the underlying pre-conflict trend), β_2 is the level change after the conflict and β_3 is the slope change after the conflict (using the interaction between time and intervention: TXt).

Appendix 2

Scatterplot of the time series showing the energy expenditure rate across Italian regions and Autonomous provinces in the period 2017-2021.

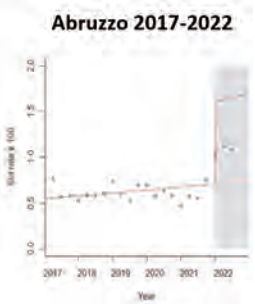


Appendix 3

The Poisson regression model and counterfactual graphs for all the Italian regions

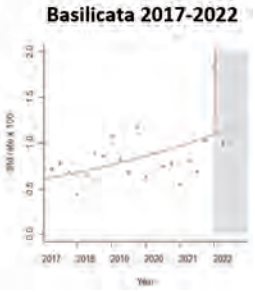
Abruzzo

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.202	0	22637.611	0 0.006	0.006	0.006
War	0.809	0	2874.674	0 2.247	2.245	2.248
Time	0.013	0	718.862	0 1.013	1.013	1.013



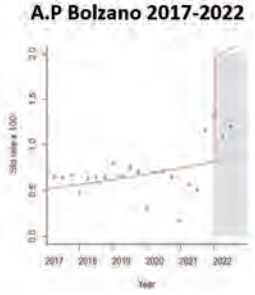
Basilicata

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.113	0	-16299.370	0 0.006	0.006	0.006
War	0.623	0	1721.057	0 1.864	1.862	1.865
Time	0.030	0	1229.485	0 1.030	1.030	1.030



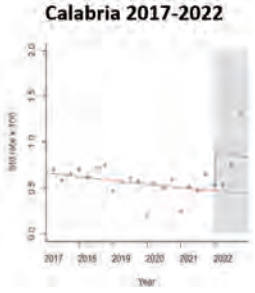
A.P Bolzano

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.254	0	-16155.072	0 0.005	0.005	0.005
War	0.877	0	2444.701	0 2.404	2.402	2.404
Time	0.022	0	895.118	0 1.023	1.023	1.023



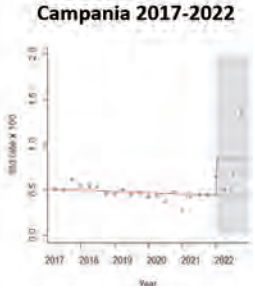
Calabria

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.002	0	-262111.791	0 0.007	0.007	0.007
War	0.643	0	2206.019	0 1.902	1.901	1.903
Time	-0.017	0	-1068.980	0 0.983	0.983	0.983



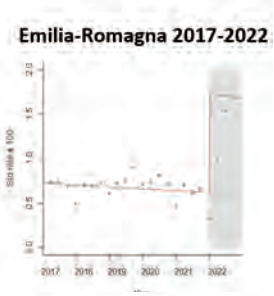
Campania

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.264	0	-42156.478	0 0.005	0.005	0.005
War	0.655	0	3700.306	0 1.925	1.924	1.926
Time	-0.008	0	-730.147	0 0.992	0.992	0.992



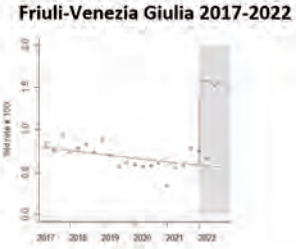
Emilia-Romagna

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-4.927	0	-44075.274	0 0.007	0.007	0.007
War	1.021	0	6953.135	0 2.777	2.776	2.778
Time	-0.008	0	-816.898	0 0.992	0.992	0.992



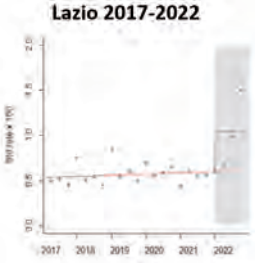
Friuli-Venezia Giulia

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-4.818	0	-23.108.741	0 0.008	0.008	0.008
War	1.004	0	3470.483	0 2.730	2.728	2.731
Time	-0.016	0	-921.313	0 0.984	0.984	0.984



Lazio

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.232	0	-45813.677	0 0.005	0.005	0.005
War	0.541	0	3531.671	0 1.719	1.718	1.719
Time	0.006	0	650.865	0 1.006	1.006	1.006



Liguria

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.844	0	-22199.011	0 0.003	0.003	0.003
War	0.517	0	1711.271	0 1.677	1.676	1.678
Time	0.033	0	1637.479	0 1.033	1.033	1.033

Lombardia

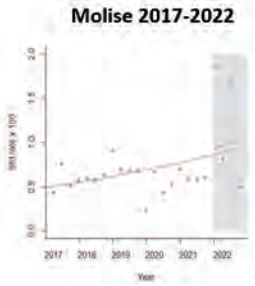
	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.237	0	-61142.892	0 0.005	0.005	0.005
War	0.488	0	4307.434	0 1.628	1.628	1.629
Time	0.009	0	1300.839	0 1.009	1.009	1.009

Marche

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.817	0	-24410.070	0 0.006	0.006	0.006
War	0.735	0	2776.962	0 2.086	2.085	2.087
Time	0.012	0	702.739	0 1.012	1.012	1.012

Molise

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.307	0	-11814.771	0	0.005	0.005	0.005
War	0.082	0	136.756	0	1.085	1.084	1.086
Time	0.028	0	807.812	0	1.029	1.028	1.029

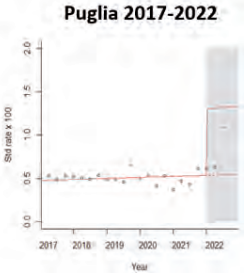


Piemonte

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-4.933	0	-41579.916	0	0.007	0.007	0.007
War	0.627	0	3591.985	0	1.871	1.871	1.872
Time	-0.012	0	-1216.017	0	0.988	0.988	0.988

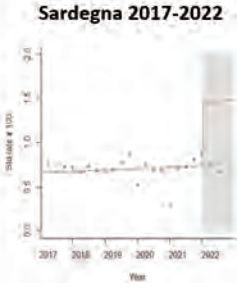
Puglia

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.339	0	-36212.518	0	0.005	0.005	0.005
War	0.890	0	4809.001	0	2.435	2.434	2.436
Time	0.006	0	464.395	0	1.006	1.006	1.006



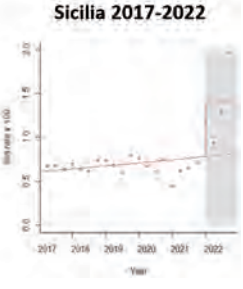
Sardegna

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.020	0	-26167.882	0	0.007	0.007	0.007
War	0.665	0	2700.280	0	1.945	1.944	1.946
Time	0.006	0	381.448	0	1.006	1.006	1.006



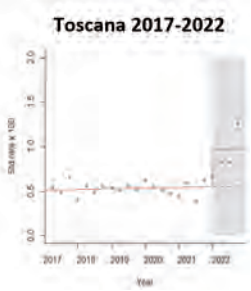
Sicilia

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.094	0	-44083.165	0	0.006	0.006	0.006
War	0.558	0	3763.989	0	1.748	1.747	1.748
Time	0.012	0	1327.414	0	1.012	1.012	1.012



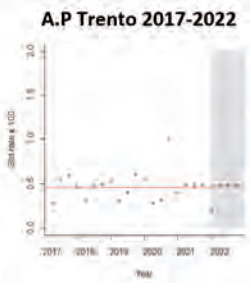
Toscana

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.271	0	-41383.683	0	0.005	0.005	0.005
War	0.553	0	3258.181	0	1.739	1.739	1.739
Time	0.004	0	374.957	0	1.004	1.004	1.004



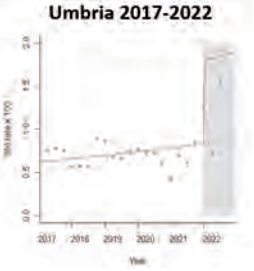
A.P Trento

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.376	0	-14155.688	0	0.005	0.005	0.005
War	0.056	0	95.328	0	1.058	1.056	1.059
Time	-0.001	0	-20.307	0	0.999	0.999	0.999



Umbria

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.079	0	-19729.715	0	0.006	0.006	0.006
War	0.768	0	2429.653	0	2.156	2.155	2.158
Time	0.014	0	704.222	0	1.014	1.014	1.015



Valle D'Aosta

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.503	0	-6567.654	0	0.004	0.004	0.004
War	0.509	0	459.998	0	1.664	1.661	1.668
Time	0.003	0	42.645	0	1.003	1.003	1.003

Veneto

	Estimate	StdErr	z	P exp (Est.)	2.5%	97.5%
(Intercept)	-5.271	0	-41383.683	0	0.005	0.005	0.005
War	0.553	0	3258.181	0	1.738	1.738	1.739
Time	0.004	0	374.957	0	1.004	1.004	1.004

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What is the Current Knowledge and Experience on Preventive Pathway for Healthy Ageing in Italy? A Scoping Review

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Keywords: Lifestyle; active ageing; preventive program; longevity
Parole chiave: Stili di vita; invecchiamento attivo; programma preventivo; longevità

Abstract

Background. *Worldwide population is ageing rapidly. Lifestyle factors are essential targets for leading to behaviour change interventions that promote healthy aging.*
Study design. *We performed a scoping review aimed to underline the current knowledge and experience on preventive interventions for healthy and active ageing in Italy. Secondly, it intended to study the manner in which this country will pursue the topic in this research area.*
Methods. *The search was conducted on different databases: PubMed, CINAHL, Embase, and Scopus on July 25th, 2023, and search results were filtered to include only articles published from 2003.*
Results. *A total of 951 potentially relevant records were retrieved. After duplicates removal, 810 unique records were screened. Finally, four studies fulfilling established criteria were included. All the studies were conducted in the northern and central regions of Italy. The investigated populations were older adults, and all four studies were focused mainly on primary prevention and health promotion strategies based on self-efficacy and motivation of the participants, including physical activity, diet and cognitive training. In addition, two studies used mobile health technologies to deliver the preventive intervention for healthy ageing.*
Conclusion. *Our scoping review underlines the limited knowledge and experience of preventive healthy aging interventions in the national setting. The new preventive pathway that promotes healthy ageing healthily should be based on tailored lifestyle interventions, managed by multidisciplinary teams with the use of digital tools, in order to improve older people's safety. The characteristics of the settings are still not clear.*

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Introduction

Worldwide population is ageing rapidly. This phenomenon, also known as the third demographic transition, will lead to a relevant increase of the number of older people. It has been estimated that the proportion of citizens in the European Union over 65 years of age will rise from 18% to 28% by 2060, and the percentage of over-80s will increase from 5% to 12% during the same period (1). Moreover, recent literature has acknowledged that the process of ageing is multifaceted and determined by a complex interaction between biological, cultural, community, and environmental aspects (2). The World Health Organization (WHO) defined active ageing as "the process of optimising opportunities for health, participation, and security in order to enhance quality of life as people age" for "helping people stay in charge of their own lives for as long as possible as they age and, where possible, to contribute to the economy and society" (3). In order to mitigate the effects of an ageing population on society, and in particular on healthcare systems, 194 countries in the world adopted the global strategy and action plan on ageing and health (2016–2030), which aimed to a full promotion of healthy ageing WHO stated that healthy ageing is "the process of developing and maintaining the functional ability (i.e., people's capabilities of being and doing what they have reason to value) that enables well-being in older age" (4). The aim of healthy ageing is not only to extend lifespan, but also to improve quality of life and both physical and mental health of older people (5). The global strategy and action plan on ageing and health is aligned with the 2030 Agenda for Sustainable Development Goals (6), which aims to ensure that every human being can fulfil their potential in dignity and equality in a healthy environment. Furthermore, aging population is a phenomenon that is observed in Italy, where 23.3% of the population is 65 years old or older, and 7.5% is 80 years or older (1). In addition, the life expectancy of Italian citizens is one of the highest in the world and not just in Europe. This position as a front-runner of ageing, together with the country's extraordinary regional social health disparities, makes Italy the ideal "empirical laboratory" to address how different combinations of biological, clinical, cultural, and socioeconomic factors are leading to different individual and social outcomes. Thus, Italy represents an exceptional context in which designing, testing, and implementing innovative solutions, and to adopt different models of intervention for prevention, health and long-term care, working arrangements, political agendas, and societal outreach. Moreover, as population is progressively ageing, we need to take into account that frailty-related conditions such as chronic diseases are rising; even if national initiatives are trying to spread health promotion and disease prevention programs and policies, people are at risk of developing diseases as they age. Access to care becomes indispensable as most of the elderly live in the community, therefore care services should be offered within primary health care settings (11). As chronic diseases are increasing and the population needs are changing, a shift from a treatment model to a coordinated and comprehensive continuum of care is needed. This will require a reorientation in health systems that are currently organised around acute, episodic experiences of disease. The present acute and chronic care models of health service delivery are inadequate to address the health needs of rapidly ageing populations (11). Looking at the practical viewpoint, health centres, primary care facilities or community setting among the national setting are implementing and integrating heath intervention designed for high-priority diseases such as diabetes, hypertension, depression, and cardiovascular diseases. In particular, inside the National Health System we have several care pathways tailored for different diseases. A "care pathway" is a way to translate evidence into practice, in order to reduce medical costs while delivering optimal patient-centred care (12). The diagnostic therapeutic care pathway is a series of predefined, structured and coordinated services performed at an outpatient and/or inpatient and/or territorial level, which provides for the integrated participation of different specialists and professionals, at the hospital level and/or a local one, in order to carry out the most appropriate diagnosis and therapy for a specific pathological situation or even the health care needed in particular life conditions (13,14). Recently, the concept of a care pathway based on health reinforced the concept of attention to aspects of prevention and proactive care of the assisted person (15); however, to date, no clear preventive pathway specifically aimed to improve active and healthy ageing exists. According to the WHO, living arrangements including social support, social wealth, and background factors (e.g., age, gender, marital status, employment status, educational background, income, size of the family) are considered influential in active and healthy ageing (16). A further fundamental factor in the vision of healthy aging is the digital aspect. Digital health is becoming important in the management of aging

and for the reform of local preventive care as stated in the Mission 6 of the National Recovery Plan and Resilience (PNRR). It is therefore strategic to understand how digital health tools can be included in the preventive pathway. To do this it is necessary to reach a consensus on the taxonomy fold, on how to evaluate digital tools, by giving a definition of their role within care pathways and by measuring patient's benefits from their use (17).

Healthy lifestyle is not the only method to promote healthy ageing, but can be an easy way (5). Lifestyle factors are essential targets for leading to behaviour change interventions that promote healthy aging; in particular physical activity, nutrition, and cognitive function are the main influential factors in active and healthy ageing (18).

In this scenario, our scoping review aimed to underline the current knowledge and experience on preventive interventions for healthy and active ageing in Italy and, secondly, to display the manner in which our country will pursue this topic on in this research area. The innovative aspect of this scoping review consists in defining the main characteristics of a preventive pathway model applied to the national contest, which can subsequently be translated, adapted and implemented in other countries. This scoping review is conducted within the Age-It Project framework, part of the National Research Plan 2021-2027 (19).

Materials and Methods

1. Study design

This scoping review (20) was conducted following the methodological framework outlined by Arksey and O'Malley (21) and it was reported according to the PRISMA extension for Scoping Reviews (22).

2. Review question

The search strategy was based on the following review question: What is the current knowledge on preventive pathway for healthy ageing in Italy? More specifically, what has already been done and how is Italy moving in this healthy ageing research area?

3. Inclusion and exclusion criteria

Eligibility criteria were established according to the PCC (Population, Concept, Content) framework (23). The review focused on studies on older adults, namely aged 60 years or older, with any health condition. Studies considering different subjects' age were included only if it was possible to isolate information about the older adults. The concept of the study was the existing preventive pathway or preventive program for healthy ageing. Moreover, this scoping review tried to understand if aspects related to acceptability of preventive pathways by older adults were considered. Studies were excluded if no clear description of preventive pathways was included. Studies conducted in both primary care and community/municipality settings were included. Research conducted outside of Italy were excluded. All studies on primary data (e.g., experimental and quasi-experimental, observational, and qualitative studies) were included. In contrast, we did not include commentaries, opinion papers, and literature syntheses.

4. Search strategy

A comprehensive search strategy was developed combined appropriate keywords, MeSH terms, and Boolean operators. The search string was: *((Pathway* OR Path OR Approach OR Percorso) AND ("Healthy Aging"[Mesh] OR "Healthy Ageing" OR "Aging Healthy" OR "Ageing Healthy" OR "Aging Well" OR "Well Aging" OR "Active Aging" OR "Active Ageing" OR "invecchiamento in salute" OR "invecchiamento sano" OR "invecchiamento attivo" OR Longevity OR Longevità OR "Health promotion" OR "Prevention Plan*" OR "Preventive Health Program*" OR "Program* Preventive Health" OR "Preventive Program*" OR "Programma preventivo" OR "Promozione della salute") AND ("Aged"[Mesh] OR elderly OR anzian* OR "giovani anziani" OR "Older Adult*") AND ("Methods"[Mesh] OR methodology OR metod* OR Metodologia OR Design OR Model* OR Modello OR Modeling OR "Model* composition"OR Polic*) AND (Italy OR Italia OR Italy [text word] OR Italian [text word] OR Italia [text word] OR Italiano [text word] OR "Italian Country" OR "Italian Region"[text word] OR "Italian Context"[text word]))*.

The search was conducted on different databases, namely Medline (PubMed), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, and Scopus. The databases were queried on July 25th, 2023; search results were filtered to include only articles in Italian or English published from 2003, as it was around this time that the WHO promoted and launched a healthy ageing campaign among the community (24). Study selection and data extraction. After removing duplicate records, title and abstract were independently screened by four reviewers (AM, IP, NC and AI). Then, full texts of relevant articles

were retrieved and independently assessed by at least two researchers. Disagreements between researchers were solved through team discussion and a fifth reviewer (AC) was involved to solve discrepancies. Eligible articles were extracted and summarised independently using a standardised form. Extracted information included: authors, publication year, location, study design, participant characteristics, study setting, involved professional figures, outcomes, preventive intervention description, key findings. Then, extracted information was double-checked by a second researcher.

5. Quality assessment

Even if scoping review guidelines do not state the mandatory phase of quality assessment, authors decided to perform the risk of bias analysis. In detail, methodological quality was assessed by four researchers (AM, IP, NC and AI) using the Joanna Briggs Institute (JBI) Critical Appraisal Checklists for Cohort Studies (25), Quasi Experimental Studies (25), and Qualitative Studies (26). The criteria to generate the overall score were decided and approved by the whole research team. In detail, the overall score was assigned as following: (i) High quality if all the criteria were met; (ii) Medium quality if one or more criteria were unclear; (iii) Low quality if one or more criteria were not met. The quality assessment was independently conducted by at least two researchers for each included study, and disagreements were resolved with the involvement of a third researcher.

Results

1. Search results

A total of 951 records were retrieved. After duplicates removal, 810 unique records were screened. Of them, 795 records were excluded based on title, abstract, and/or portion of text. Then, 15 studies were eligible for full-text screening. Finally, four studies fulfilling established criteria were included. Figure 1 shows the PRISMA-ScR flowchart (27). The main reason for exclusion was the topic not matching the research question.

2. Quality assessment

Quality assessment summary is presented in Table 1.

In detail, the quasi-experimental study performed by Antonietti et al. (28) was scored as medium quality for the inappropriate statistical analysis used and for unclear participants follow-up. The cross-sectional study published by Bortoluzzi et al. (29) was classified as a medium quality due to the lack of strategies to deal with confounding factors. The qualitative study conducted by Rampioni et al. (30) was classified as medium quality level considering the absence of

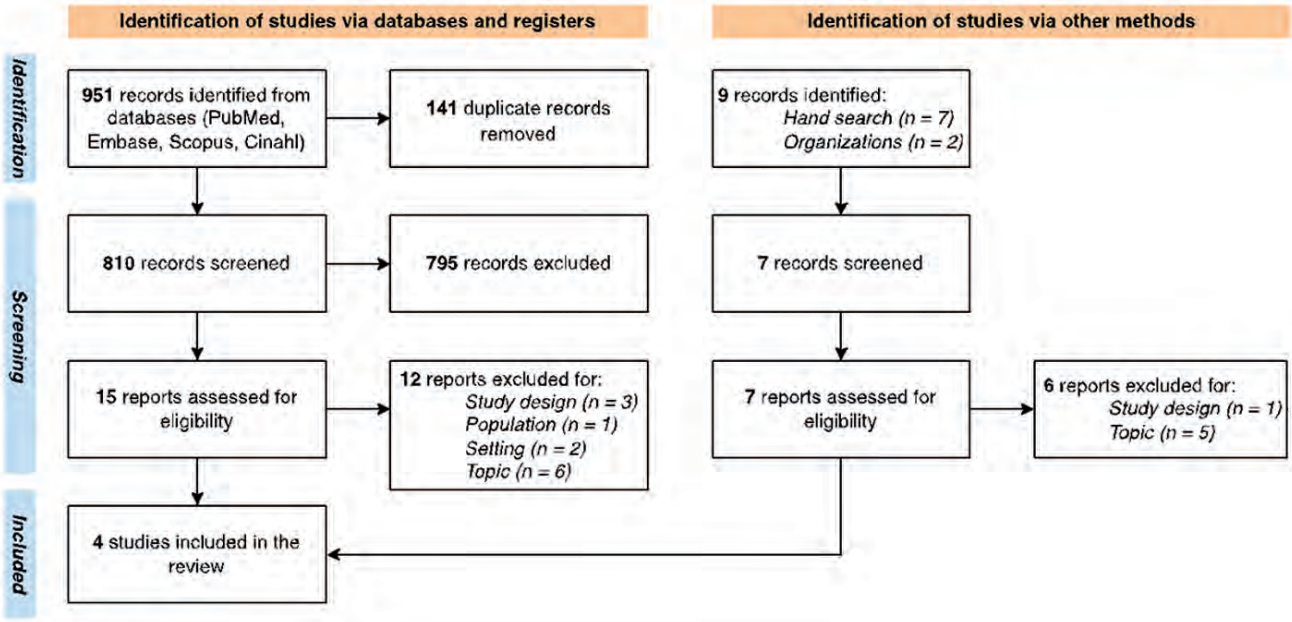

Figure 1. PRISMA flowchart.

Table 1 - Quality assessment of the included studies.

Article	Study design	Assessment tool	Overall quality
Antonietti et al., 2014	Quasi experimental	JBI for Quasi-experimental	Medium
Bortoluzzi et al., 2022	Cross sectional	JBI for Cross Sectional	Medium
Rampioni et al., 2021	Qualitative	JBI for Qualitative	Medium
Santini et al., 2020	Qualitative	JBI for Qualitative	Low

ethical committee approval and the unclear statement locating researchers culturally or theoretically. Finally, the qualitative study performed by Santini et al. (31) was scored as low quality for no evidence of ethical approval by an appropriate body, for unclear statement locating the researcher culturally or theoretically, and for unclear influence of the researcher on the research and vice-versa.

3. General characteristics

Studies characteristics and data extraction of the included studies are shown in Table 2, while Table 3 presented the mail outcomes and results obtained in each included study. Antonietti et al. (28) and Bortoluzzi et al. (29) conducted their studies in the cities of Milan and Vercelli (northern Italy), respectively. Santini et al. (31) and Rampioni et al. (30) settled the intervention in Ancona (centre Italy). Santini et al. (31) and Rampioni et al. (30) tested digital methods (e.g., computer and sensing technologies) for active and healthy ageing and digital health coaching technologies. The quasi-experimental study conducted by Antonietti et al. (28) aimed to evaluate four different healthy ageing strategies integrated in a cohesive empowerment pathway to enhance life skills of older people. The aim of the study conducted by Bortoluzzi et al. (29) was to evaluate the effectiveness of the Dedalo Project, a community multicomponent intervention promoting healthy ageing. The research involved 365 participants with an average age of 60 years, living in Vercelli. Rampioni et al. (30) conducted a qualitative research on active and healthy ageing technologies. The study aimed to gather and evaluate the viewpoints of older adults, caregivers, and stakeholders in the care and technology sectors. The research focused on a range of devices designed to support healthy ageing and independent living. A sample of 30 participants, including 13 patients, eight caregivers, and nine stakeholders were enrolled. Finally, Santini et al. (31) carried out a qualitative study on the benefits of a digital coach in enabling healthy ageing for older adults who are transitioning into retirement. The study involved 15 participants, including five older workers, five retirees, and five colleagues. The primary objective of this study was to explore the potential of digital health coaching systems in promoting healthy ageing among older adults.

The preventive pathway characteristics are described in Table 2. The four preventive pathways described were heterogeneous but all focused on lifestyle interventions.

4. Preventive pathway characteristics from quantitative studies

Particularly, the intervention proposed by Antionetti et al. (28) consisted in an “empowerment pathway” including four main actions: cognitive and brain stimulation, theory of mind and decision making, framing effects of communication on healthy eating, and nutrition. The pathway aimed to identify which messages were more effective in activating behavioural intentions that can lead to better health and well-being of the older people. With regards to cognitive and brain stimulation, preliminary evidence suggested an improvement in performance after the cognitive/neuromodulation process. In terms of decision making, the subjects were strongly oriented towards fair behaviour when taking decisions about financial issues. With regards to healthy eating, participants’ intentions to eat more or less of different foods in the future depend on both the framing of persuasive messages and individual differences in self-efficacy and regulatory focus. For example, messages describing the positive consequences for well-being when meat consumption was limited weremore effective than messages describing the negative consequences of frequent meat consumption. However, the effectiveness of message framing was moderated by diet-related self-efficacy. Among participants with low self-efficacy, messages describing the positive consequences reduced the intention of eating meat, more than messages describing the negative consequences. Among participants with high self-

Table 2 - Studies characteristics and data extraction

Author, years and country	Study Design	Participants characteristic (Age, gender)	Preventive pathway intervention	Study Setting	Involved professionals figures
Antonietti A, et al. 2014	1 Phase: quasi-experimental design 2 Phase: quasi-experimental design 3 Phase: qualitative design	Age: 65 years old	**Empowerment pathway:** 1) Cognitive and brain stimulation 2) Theory of Mind and Decision-Making 3) Framing effects of communication on healthy eating and nutrition, (4) Engaging the elderly in pleasant activities to enhance emotional, social and cognitive skills	Department of Psychology of the Catholic University of the Sacred Heart of Milan	Research team Psychologists
Bortoluzzi S, et al. 2022	Cross sectional study	N=369 Total participants EG: N=155, 58.97±8.84 CG: N=214, 57.59±10.09	**Dedalo Project:** Four preventive path focus on healthy diet, physical exercise, socialization and culture, and discovery of the local territory.	Vercelli municipality	Vercelli Local Health, University, Organization
Rampioni M, et al. 2021	Qualitative Study	N= 30 Total Participants N=13 Patients, age:78.31 (6.62), Male 84.61% N=8 caregivers 51.8 (11.06), Male 50% N=9 stakeholder, age: 43.67 (17.73), Male 33.3%	**The SAVE system** Dygital solution to support end users in staying in their familiar environments for as long as possible, exercising their autonomy and self-management, and avoiding social isolation.	INRCA	Reasearch Team Psychologysts
Santini S, et al. 2020	Qualitative	N=15 Total participants; N=5 Older workers; N=5 Retirees; N=5 Colleagues; Mean: 59.8 years	**AgeWell Project:** Online digital health promotion programs: diet behavior, physical activity, and social inclusion. Virtual coaching to support a healthy and meaningful life of older adults and employees in their retirement process.	INRCA	Research team

efficacy, both types of messages were associated with reduced future intentions to eat meat, suggesting that those who believed they could follow a healthy diet were easily motivated by both gain-framed and loss-framed messages. The success of health and nutrition messages for older people individuals relied on matching the message delivery with the receivers' abilities.

The Dedalo project conducted by Bortoluzzi et al. (29) was a multifaceted initiative that used social marketing and community coalitions to promote healthy lifestyles through four main categories. The "good diet, good health" path, was designed to provide information on how to adopt a healthy diet through the organisation of cooking courses, workshops, seminars, and thematic dinners. The "Let's work out together" path, encouraged collective exercise by offering gym classes, walking groups, and martial art courses. The "Surprise and amazement" pathway aims to encourage socialising and cultural participation through museum

Table 3 - Outcomes and results

Study	Physical activity	Health status	Psychosocial status	Wellbeing	Food, smoking, and drinking habits	Cognitive/mental status	Other outcomes	Main Results
Antonietti A, et al. 2014	-	Subjective perception of daily functioning improvements	-	-		Improvements in performance on memory-related tasks, enhancements in executive functioning, particularly in non-verbal tasks. Assessment of the ability to understand the intentions and emotions of self and others. Fairness perceptions and risk attitudes using the Ultimatum Game and questionnaires	-	**Cognitive and brain stimulation** Improved performance after the cognitive/neuromodulation process of empowerment in determined cognitive areas. **Theory of mind and decision making** Subjects are strongly oriented towards a fair behaviour in the decision of the division of money **Healthy eating** Participants' intention to eat more or less depends both on the framing of the persuasive messages and on individual differences in self-efficacy and regulatory focus. Participants with low self-efficacy, messages describing the positive consequences of limited meat consumption reduce the intention to eat red meat more than messages describing the negative consequences. Among participants with high self efficacy both types of messages are associated with reduced intention to eat meat in the future, indicating that those who believe to be able to follow a healthy diet are easily motivated by both gain-framed and loss-framed messages. **Engaging** Interventions based on music may promote improvements in the elderly.

Study	Physical activity	Health status	Psychosocial status	Wellbeing	Food, smoking, and drinking habits	Cognitive/mental status	Other outcomes	Main Results
Bortoluzzi S, et al. 2022	Moderate and high-intensity physical activity duration and frequency	Self-reported diseases, body mass index	Life satisfaction, number of unhealthy days reported in the past month	Overall well-being and satisfaction measures associated with participation in the Dedalo project	Daily intake of fruits and vegetables, consumption of sugar drinks, frequency of smoking, Daily alcohol intake	-	-	The Dedalo project was mainly attended by women. They had a higher SES and they were healthier than general population. Participants self-reported most often a medium–high level of life satisfaction, a higher number of unhealthy days for psychological conditions, less diagnosis of myocardial infarction, arthrosis but more diagnosis of cancer. Participants in the Dedalo project were less exposed to all the analysed risk factors. The percentage of individuals reporting high levels of "life satisfaction" was higher in Dedalo group than the control.
Rampioni M, et al. 2021	-	-	-	-	-	-	Learnability, security, independence, coaching values and impact of the proposed technology	Older adults recognized the importance of a system that not only reduces the effort to learn something new and complex, but also reduces the need to ask a relative and/or a friend for help. They stressed the need for the system to be able to not only protect users' vulnerabilities and security, but also to support them in maintaining their abilities and to make them feel as active and determined as possible.
Santini S, et al. 2020	Improvement in frequency and intensity of physical activity.	-	Improvement in social interactions and quality of life themes post-intervention.	-	-	Assessment of enhanced cognitive capabilities through various measures	Associated risks such as stigma and privacy concerns regarding digital health coaching	Older adults were likely to use a digital health coach to stay healthy before and after retirement. The digital health coach was expected to provide them with information about social and cultural events and the rights of older people and pensioners. They would also like a coach that could adapt to their needs and motivate them to a healthy lifestyle

visits, reading experiences, and active theatre and music experiences. Meanwhile, the "Discovery of the territory" path, aimed to promote active life and the discovery of territory by organising events such as hiking or walking in local forests and natural parks. The instruction was carried out in the form of meetings and classes. The evaluation study showed results in smoking and diet, physical activity, alcohol intake, body mass index, cognitive activity, socialising, and well-being. The participants of the Dedalo project reported a medium-high level of life satisfaction and experienced more days of poor mental health than the control group. Participants in the Dedalo project were less exposed to all the assessed risk factors.

5. Preventive pathway characteristics from qualitative studies

In the qualitative study conducted by Rampioni et al. (30) the proposed intervention was based on the SAVE system. The SAVE system is a platform that used several smarthome and wearable sensors. These sensors streamed to a cloud-based platform where algorithms detected any changes in behaviour and physiology. Authors identified six main areas that communication/sensing technology should concentrate on: ease of use, safety, autonomy, empowerment, guidance principles, isolation, habit and cultural impact, and personalised solutions. Digital solution helped people to stay in their own homes for as long as possible, while maintaining their independence, managing their own care, and avoiding loneliness. They also assisted family caregivers in providing the necessary assistance while balancing their personal and professional lives. This study was aligned with the Active Aging framework and considered factors that influenced how useful and beneficial information and communication technologies are to promote healthy and active ageing in older adults.

Finally, Santini et al. (31) designed a preventive intervention based on "The AgeWell digital health coach"; these systems could potentially delay the need for intensive care and improve individuals' independence over time. The AgeWell digital health coach was a software that looked and behaved like a human. Older people were likely to use a digital coach to stay healthy in their retirement. They expected the coach to provide information about cultural and social events, along with the rights and benefits of pensioners. Moreover, they required a coach that could adjust to their specific needs and motivate them towards a healthy lifestyle. The focus groups identified the necessary preventive intervention, which included online promotion programs for healthy dietary behaviour, physical activity, and social inclusion. Moreover, virtual coaching was used to support older adults and employees in their retirement process to promote a healthy and purposeful life.

6. Study setting and professional figures involved

Study setting and professional figures involved in the preventive pathway are displayed in Table 2.

The project conducted by Bortoluzzi et al. (29) was settled in the community and aimed to create networks and it involved local stakeholders in providing preventive opportunities for the population. This includes building networks, coordinating actors and communicating Dedalo events to the population. The study conducted by Antonietti et al. (28) was carried mainly in a scientific and controlled University setting. The other two included studies (30,31) were both conducted by the National Institute of Health and Science on Aging (INRCA) based in Ancona, a public organisation that oversees five geriatric hospitals and residential care facilities in Italy. INRCA is dedicated to conducting clinical, biological, and socioeconomic research on ageing. Therefore, INRCA had various professionals holding different roles, including office workers, nurses, doctors, therapists, administrators, biologists, as well as gerontologists, geriatricians, and biologists. Rampioni et al. (28) involved a multidisciplinary team of two psychologists, one user-centred design expert, and two engineers that carried out iterative work to interpret the data, while Santini et al. (29) created a virtual coaching used to support older adults and employees in their retirement process to promote a healthy and purposeful life adjusting the specific needs of older adults and motivate them towards a healthy lifestyle.

Discussion

This scoping review aimed to explore the current knowledge and experience on preventive pathways for healthy and active ageing in the Italian setting. Our results summarized the available information regarding existing preventive pathways in Italy. Moreover, it displayed the manner in which this country will pursue this topic in the future through the PNRR, which is promoted by the European community.

As regards the structure of the existing preventive pathway, all four studies were coherent with the WHO definition of "healthy aging". In all the included studies healthy ageing took into account cognitive

functioning, social and productive functionality, life satisfaction, and well-being. Only Bortoluzzi et al. (29), in addition to the previous elements, took into consideration health status (diseases, taking medications and self-monitoring of blood pressure). This description of healthy ageing was in line with the aim of prevention and health promotion programs around the world (4). In this scenario, programs were able to empower elder people to pursue healthy aging by, preventing, for example, social isolation or throughout the assistance of effective integrated social services, limiting interventions carried out by the National Health Service. A shift from a hospital-centre model to a community-centred care approach is crucial. Therefore, it becomes important to address people's needs before they access healthcare/welfare settings, when they already have a significant burden of illness and disability.

The main interventions proposed in the preventive pathway were primary prevention and health promotion programs, such as physical activity and diet adherence. These were similar to the ones described in the WHO global action plan for healthy ageing (32) and in recent international literature that show how lifestyle interventions represent an effective solution in public health (5). Physical activity and nutritional intervention can contribute to remaining healthy and to improve physical and mental health. It is well known that PA is a powerful tool for the prevention of non-communicable diseases, through reduction of main risk factors (33). Moreover an emerging line of research investigated the efficacy of lifestyle interventions also in improving cognitive functions or preventing the cognitive decline of individuals suggesting positive results (34).

In addition, preventive pathways should take into account the level of self-efficacy and motivation of the participants. Among the included studies only Antionetti et al. (28) took into consideration self-efficacy aspects in order to adapt the interventions to the specific health needs and state of awareness of the patient. As suggested by the recent randomised control trial published by Taksler et al. (35), it is necessary to tailor preventive interventions based on the participant's willingness; what am I supposed to do to improve my health? this is the future to create personalised disease prevention programs for healthy ageing. Among the four included studies, Rampioni et al. (30) and Santini et al. (31) used mobile health intervention which showed important health benefits in terms of improving healthy ageing. These preliminary results suggest an increasing interest in technology-based health programs. In outlining a preventive pathway aimed at healthy ageing it will therefore be necessary to take into consideration the growing presence of interventions that involve the use of technology (36-38). Also the European commission published a communication on "enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society", suggesting the use of advance digital tools to support integrated care. Moreover, the Ministerial Decree 77/2022 (39) has reorganised Italian territorial healthcare assistance according to a new model through the developing of new services and functions, such as community homes, community hospitals, and primary care operating centres. Furthermore, it is highlighted the importance of home as the first place of care and the need of implementing telemedicine service that provide assistance through the use of digital devices., Nevertheless, these services should be quickly implemented in the new developed preventive pathways. In the two studies (30,31) where digital technology is used, focus groups were fundamental to bring the intervention closer to a real application, where the intervention itself is fully accepted and can therefore produce the desired effects. These interventions are included in policies for active ageing in Italy (40), in alignment with the Madrid International Plan of Action on Ageing (41). Digital literacy in the elder counteracts marginalisation and encourages their participation in society, which is an element of advantage for healthy ageing.

As far as concern the setting and the professional figures involved Bortoluzzi et al. (29), with the Dedalo project, gave evidence of the importance of various stakeholders, public and private entities that operated at a local level for the benefit of the older people (Regions, local authorities, third sector organisations, etc.). Local and regional initiatives should in fact encourage communication and interaction between the various actors involved in the process, including Regions (42). However, it appears that the settings studied aren't feasible to provide models that can be used in real contests. Apart from the Dedalo Project (29), which is based on a specific community program, the other projects were mainly confined to the research field. The professional figures involved in the preventive pathway were still unclear and heterogeneous. Recent scientific evidence suggests that family and community nurses, psychologists, kinesiologists, and nutritionists play a fundamental role in the promotion and prevention of health in several target populations (43,44).

Study Limitation and future direction

It is worth mentioning that this scoping review presents some limitations. First of all, the small number of included studies. Today the topic of healthy ageing is addressed by various task forces and in several European projects (i.e., Erasmus Sport Plus Project). However, to date these projects have not produced scientific evidence or practical experiments on Italian territory. In addition, many studies focused on individual lifestyle interventions (supervised physical activity programs, dietary changes, fall prevention) (45-48) without inserting these lifestyle interventions into structured pathways. Moreover, we decided to focus our scoping review only on studies conducted in Italy due to the fact that we are interested in understanding what is the current knowledge and experience on preventive pathways for Healthy ageing in our national contest; however we believe that our results can be useful for the creation of a new preventive pathway for healthy ageing in other countries; especially because a clear definition of this pathway for prevention does not exist even in the international scenario. At the same time, many Italian projects (i.e., SUNFRAIL, SPRINTT) based on healthy ageing are focused on specific diseases or on subjects with high clinical complexity that require hospital supervision (49). Nowadays, as suggested by the small number of articles found, preventive pathways have not received enough attention; therefore, research should move toward defining practice models that are effective in local contexts. Then, a systematic review more focused on effectiveness and sustainability of this preventive pathway inside an international context would take place. Recently a new project financed by the National Recovery and Resilience Plan (PNRR) named Age-It focused on addressing the consequences and challenges posed by the ageing population in Italy (50). A multifaceted and complex process that presents risks, but also opportunities to promote inclusive well-being with implications for the entire society. The project involves public and private partners with an interdisciplinary approach, to contribute to this field of research and support the development of related goods and services for the market.

Conclusions

Our scoping review underlines the limited knowledge and experience of preventive healthy aging interventions in the national setting. The new preventive pathway aimed to healthy ageing should be based on lifestyle interventions (i.e., physical activity, nutrition and cognitive training), managed by multidisciplinary teams (i.e., family and community nurse, psychologists, kinesiologists, nutritionists) with the use of digital tools (i.e., mobile health, digital coach) in order to improve the safety of older people. The setting characteristic is not clear, future study should be focused on how to implement this type of intervention outside a research context. Finally, one of the main challenges is the participation of this type of population in preventive intervention. Therefore, effective strategies are needed to promote engagement in care, tailored to the needs of older people. These main characteristics of a preventive pathway model applied in the national contest could be subsequently translated, adapted and implemented in other countries.

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Riassunto

Quali sono le attuali conoscenze ed esperienze in merito ad un percorso preventivo per l'invecchiamento in buona salute in Italia? Una revisione scoping

Introduzione. La popolazione mondiale sta invecchiando rapidamente. I corretti stili di vita sono obiettivi fondamentali per interventi orientati al cambiamento del comportamento per promuovere un invecchiamento in buona salute.

Disegno dello studio. Abbiamo condotto una revisione scoping con l'obiettivo di sottolineare le attuali conoscenze ed esperienze in merito a interventi preventivi per l'invecchiamento sano e attivo in Italia e il modo in cui il nostro paese si muoverà in quest'area di ricerca.

Metodi. La ricerca è stata condotta su diversi database: PubMed, CINAHL, Embase e Scopus sino al 25 luglio 2023 e i risultati della

ricerca sono stati filtrati per includere solo articoli pubblicati a partire dal 2003**.**

Risultati. Sono stati recuperati un totale di 951 record potenzialmente rilevanti. Dopo la rimozione dei duplicati, sono stati sottoposti a screening 810 record univoci. Infine, sono stati inclusi quattro studi che soddisfacevano i criteri stabiliti. Tutti gli studi sono stati condotti nelle regioni del Nord e del Centro Italia. La popolazione indagata era composta da anziani e tutti e quattro gli studi si sono concentrati principalmente su strategie di prevenzione primaria e promozione della salute basate sull'autoefficacia e sulla motivazione dei partecipanti nei confronti dei corretti stili di vita, in particolare, attività fisica, dieta e allenamento cognitivo. Inoltre, due studi hanno utilizzato dispositivi digitali per veicolare un intervento preventivo per un invecchiamento in buona salute.

Conclusioni. La nostra revisione scoping sottolinea la limitata conoscenza ed esperienza esistente nel contesto nazionale riguardo agli interventi preventivi per l'invecchiamento in buona salute tra le persone anziane. Il nuovo percorso preventivo finalizzato all'invecchiamento in buona salute dovrebbe basarsi su interventi personalizzati sullo stile di vita, gestiti da team multidisciplinari con l'uso di strumenti digitali, al fine di migliorare la sicurezza delle persone anziane. Le caratteristiche del setting di implementazione del percorso preventivo non sono ancora chiare.

References

1. Decade of healthy ageing: baseline report. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. Available from: https://www.who.int/publications/i/item/9789240017900 [Last accessed: 2024 Oct 31].
2. Navarro C, Salazar J, Díaz MP, Chacin M, Santeliz R, Vera I, et al. Intrinsic and environmental basis of aging: A narrative review. Heliyon. 2023 Jul 18;**9**(8):e18239. https://doi.org/10.1016/j.heliyon.2023.e18239. PMID: 37576279; PMCID: PMC10415626.
3. Cristea M, Noja GG, Stefea P, Sala AL. The Impact of Population Aging and Public Health Support on EU Labor Markets. Int J Environ Res Public Health. 2020 Feb 24;**17**(4):1439. https://doi.org/10.3390/ijerph17041439. PMID: 32102277; PMCID: PMC7068414.
4. World Health Organization (WHO). World report on ageing and health. World Health Organization; 2015. ISBN: 9789241565042. Available from: https://www.who.int/publications/i/item/9789241565042 [Last accessed: 2024 Oct 31].
5. eBioMedicine. Healthy ageing begins with a healthy lifestyle. EBioMedicine. 2023 Mar;**89**:104528. https://doi.org/10.1016/j.ebiom.20 23.104528. PMID: 36907646; PMCID: PMC10025755.
6. Dugarova E. Ageing, older persons and the 2030 agenda for sustainable development. United Nations Development Programme. New York; 2017. Available from: https://www.undp.org/publications/ageing-older-persons-and-2030-agenda-sustainable-development [Last accessed: 2024 Oct 31].
7. Barbabella F, Cela E, Di Matteo C, Socci M, Lamura G, Checcucci P, et al. New Multilevel Partnerships and Policy Perspectives on Active Ageing in Italy: A National Plan of Action. Int J Environ Res Public Health. 2020 Dec 21;**17**(24):9585. https://doi.org/10.3390/ijerph17249585. PMID: 33371404; PMCID: PMC7767416.
8. Barbabella F, Cela E, Socci M, Lucantoni D, Zannella M, Principi A. Active Ageing in Italy: A Systematic Review of National and Regional Policies. Int J Environ Res Public Health. 2022 Jan 5;**19**(1):600. https: //doi.org/10.3390/ijerph19010600. PMID: 35010853; PMCID: PMC8744907.
9. Timonen, V. Beyond Successful and Active Ageing: A Theory of Model Ageing; Policy Press: Bristol, UK; 2016. ISBN 978-1447330172.
10. Lucantoni D, Principi A, Socci M, Zannella M, Barbabella F. Active Ageing in Italy: An Evidence-Based Model to Provide Recommendations for Policy Making and Policy Implementation. Int J Environ Res Public Health. 2022 Feb 26;**19**(5):2746. https://doi.org/10.3390/ijerph19052746. PMID: 35270438; PMCID: PMC8910036.
11. Barceló A, Epping-Jordan J, Orduñez, P, Luciani S, Agurto I, Tasca, R. Innovative care for chronic conditions: Organizing and delivering high quality care for chronic noncommunicable diseases in the Americas. Washington, DC: Pan American Health Organization; 2013. ISBN 978-92-75-117385. Available from: https://iris.paho.org/bitstream/handle/10665.2/18639/9789275117385_eng.pdf?sequence=1&isAllowed=y [Last accessed: 2024 Oct 31].
12. Ratti M, Milicia O, Rescinito R, Coeckelberghs E, Seys D, Vanhaecht K, et al. The determinants of expert opinion in the development of care pathways: insights from an exploratory cluster analysis. BMC Health Serv Res. 2023 Mar 3;**23**(1):211. https://doi.org/10.1186/s12913-023-09139-7. PMID: 36869326; PMCID: PMC9983158.
13. PNLG. Manuale metodologico. Come produrre, diffondere e aggiornare raccomandazioni per la pratica clinica. Zadig, Maggio 2002. Available from: https://www.radioterapiaitalia.it/wp-content/uploads/2017/01/Manuale_PNLG_0.pdf [Last accessed: 2024 Oct 31]
14. Raccomandazioni per la costruzione di Percorsi Diagnostico Terapeutici Assistenziali (PSDTA) e Profili Integrati di Cura (PIC) nelle Aziende Sanitarie della Regione Piemonte, AReSS, 2007. Available from: https://www.epicentro.iss.it/igea/raccolta/Allegati/Piemonte/RaccomandazioniPDTA-PIC_2007.pdf. [Last accessed: 2024 Oct 31].
15. Manuale metodologico Linee di indirizzo per lo sviluppo dei Percorsi di Salute e Diagnostico-Terapeutici Assistenziali Direzione Sanità Settore Programmazione dei Servizi Sanitari e Socio-Sanitari. Versione Dicembre 2023.
16. World Health Organization (WHO). Integrated care for older people (ICOPE) implementation framework: guidance for systems and services. World Health Organization; 2019. ISBN: 9789241515993. Available from: https://iris.who.int/bitstream/handle/10665/325669/9789241515993-eng.pdf?sequence=1 [Last accessed: 2024 Oct 31].
17. Calabria S, Piccinni C, Recchia G, Santoro E, Grigolo S, Martini N. Applicazioni della digital medicine ai PDTA: tassonomia, metodologia, impatto sul paziente e barriere

da superare [Applications of digital medicine to care pathways: taxonomy, methods, impact on patients, barriers to overcome.]. Recenti Prog Med. 2022 Feb;**113**(2):105-113. Italian. doi: 10.1701/3748.37314. PMID: 35156953.
18. Mendoza-Ruvalcaba NM, Arias-Merino ED. "I am active": effects of a program to promote active aging. Clin Interv Aging. 2015 May 5;10:829-37. https://doi.org/10.2147/cia.s79511. PMID: 26005337; PMCID: PMC4427596.
19. Ministero dell Università e della Ricerca (MUR). Programma nazionale per la ricerca 2021-2027. Available from: https://www.mur.gov.it/sites/default/files/2021-01/Pnr2021-27.pdf [Last accessed: 2024 Oct 31].
20. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol. 2018 Nov 19;**18**(1):143. https://doi.org/10.1186/s12874-018-0611-x. PMID: 30453902; PMCID: PMC6245623.
21. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. International J Soc Res Methodol. 2005(1);**8**:19-32. https://doi.org/10.1080/1364557032000119616.
22. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med. 2018 Oct 2;**169**(7):467-473. https://doi.org/10.7326/m18-0850. Epub 2018 Sep 4. PMID: 30178033.
23. Pollock D, Peters MDJ, Khalil H, McInerney P, Alexander L, Tricco AC, et al. Recommendations for the extraction, analysis, and presentation of results in scoping reviews. JBI Evid Synth. 2023 Mar 1;**21**(3):520-532. https://doi.org/10.11124/jbies-22-00123. PMID: 36081365.
24. World Health Organization (WHO). Active ageing: A policy framework. World Health Organization; 2002. Available from: https://iris.who.int/handle/10665/67215 [Last accessed: 2024 Oct 31].
25. Aromataris E, Munn Z, eds. JBI Manual for Evidence Synthesis. Joanna Briggs Institute; 2020. https://doi.org/10.46658/jbimes-20-08.
26. Lockwood C, Munn Z, Porritt K. Qualitative research synthesis: methodological guidance for systematic reviewers utilizing meta-aggregation. Int J Evid Based Healthc. 2015 Sep;**13**(3):179-87. https://doi.org/10.1097/xeb.000000000000 0062. PMID: 26262565.
27. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021 Mar 29;**372**:n71. https://doi.org/10.1136/bmj.n71. PMID: 33782057; PMCID: PMC8005924.
28. Antonietti A, Balconi M, Catellani P, Marchetti A. Empowering skills for an active ageing and healthy living. In: Active ageing and healthy living. IOS Press; 2014: 157-171.
29. Bortoluzzi S, Coppo A, Alessi D, Parovina S, Napoletano S, Ammazzagatti I, et al; DEDALO Coordinating Group. The Dedalo Project, a Community-based Prevention Program for the Promotion of Healthy Behaviors in Adult Population: Model Description and Target Population Assessment. J Prev (2022). 2022 Oct;**43**(5):639-658. https://doi.org/10.1007/s10935-0 22-00693-0. Epub 2022 Jul 14. PMID: 35834152; PMCID: PMC9281316.
30. Rampioni M, Mo oi AA, Rossi L, Moraru SA, Rosenberg D, Stara V. A Qualitative Study toward Technologies for Active and Healthy Aging: A Thematic Analysis of Perspectives among Primary, Secondary, and Tertiary End Users. Int J Environ Res Public Health. 2021 Jul 14;**18**(14):7489. https://doi.org/10.3390/ijerph18147489. PMID: 34299940; PMCID: PMC8308090.
31. Santini S, Galassi F, Kropf J, Stara V. A Digital Coach Promoting Healthy Aging among Older Adults in Transition to Retirement: Results from a Qualitative Study in Italy. Sustainability. 2020 Sep 8;**12**(18):7400. https://doi.org/10.3390/su12187400.
32. Global strategy and action plan on ageing and health 2016-2020: towards a world in which everyone can live a long and healthy life. In: World Health Organization (WHO). Sixty-ninth World Health Assembly, Geneva, 23-29 May 2016. Resolutions and decisions, annexes. Geneva: World Health Organization; 2016:8-11 WHA69/2016/REC/1. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69-REC1/A69_2016_REC1-en.pdf#page=1 [Last accessed: 2024 Oct 31].
33. De Santi M, Contisciani D, Baldelli G, Brandi G, Schiavano GF, Amagliani G. Physical activity as a tool for health promotion: the evolution of international strategies and interventions. Ann Ist Super Sanita. 2020 Oct-Dec;**56**(4):419-429. doi: 10.4415/ANN_20_04_03. PMID: 33346167.
34. Ding Z, Leung PY, Lee TL, Chan AS. Effectiveness of lifestyle medicine on cognitive functions in mild cognitive impairments and dementia: a systematic review on randomized controlled trials. Ageing Res Rev. 2023;**86**:101886. doi: 10.1016/j.arr.2023.101886
35. Taksler GB, Le P, Hu B, Alberts J, Flynn AJ, Rothberg MB. Personalized Disease Prevention (PDP): study protocol for a cluster-randomized clinical trial. Trials. 2022 Oct 22;**23**(1):892. https://doi.org/10.1186/s13063-022-06750-7. PMID: 36273151; PMCID: PMC9587586.
36. Cajamarca G, Proust V, Herskovic V, Cádiz RF, Verdezoto N, Fernández FJ. Technologies for Managing the Health of Older Adults with Multiple Chronic Conditions: A Systematic Literature Review. Healthcare (Basel). 2023 Nov 3;**11**(21):2897. https://doi.org/10.3 390/healthcare11212897. PMID: 37958041; PMCID: PMC10648176.
37. Zheng S, Edney SM, Goh CH, Tai BC, Mair JL, Castro O, et al. Effectiveness of holistic mobile health interventions on diet, and physical, and mental health outcomes: a systematic review and meta-analysis. EClinicalMedicine. 2023 Nov 18;**66**:102309. https://doi.org/10.1016/j.eclinm.2023.102309. PMID: 38053536; PMCID: PMC10694579.
38. Buyl R, Beogo I, Fobelets M, Deletroz C, Van Landuyt P, Dequanter S, et al. e-Health interventions for healthy aging: a systematic review. Syst Rev. 2020 Jun 3;**9**(1):128. https://doi.org/10.1186/s13643-020-01385-8. PMID: 32493515; PMCID: PMC7271471.

39. Ministero della Salute, Italy. DM 23 maggio 2022, n. 77. Regolamento recante la definizione di modelli e standard per lo sviluppo dell'assistenza territoriale nel Servizio sanitario nazionale. (22G00085). Gazzetta Ufficiale della Repubblica Italiana. Serie Generale n. 144 del 22 giugno 2022. Available from: https://www.gazzettaufficiale.it/eli/gu/2022/06/22/144/sg/pdf [Last accessed: 2024 Oct 31].
40. Presidenza del Consiglio dei Ministri, Dipartimento per le politiche della famiglia, Italy. Progetto di coordinamento nazionale partecipato multilivello delle politiche sull'invecchiamento attivo. Available from: https://famiglia.governo.it/it/politiche-e-attivita/invecchiamento-attivo/accordo-con-lirccs-inrca-di-ancona/scheda-progetto/ [Last accessed: 2024 Oct 31].
41. United Nations. Political declaration and Madrid international plan of action on ageing. Second World Assembly of Aging. Madrid, Spain 8-12 April 2002. New York: United Nations; 2002. Available from: https://social.un.org/ageing-working-group/documents/mipaa-en.pdf [Last accessed: 2024 Oct 31].
42. Franse CB, Zhang X, van Grieken A, Rietjens J, Alhambra-Borrás T, Durá E, et al. A coordinated preventive care approach for healthy ageing in five European cities: A mixed methods study of process evaluation components. J Adv Nurs. 2019 Dec;**75**(12):3689-3701. https://doi.org/10.1111/jan.14181. Epub 2019 Oct 6. PMID: 31441529.
43. Longobucco Y, Ricci M, Scrimaglia S, Camedda C, Dallolio L, Masini A. Effects of School Nurse-Led Interventions in Collaboration with Kinesiologists in Promoting Physical Activity and Reducing Sedentary Behaviors in Children and Adolescents: A Systematic Review. Healthcare (Basel). 2023 May 26;**11**(11):1567. https://doi.org/10.3390/healthcare11111567. PMID: 37297707; PMCID: PMC10252598.
44. Scrimaglia S, Ricci M, Masini A, Montalti M, Conti A, Camedda C, Panella M, Dallolio L, Longobucco Y. The Role of Family or Community Nurse in Dealing with Frail and Chronic Patients in Italy: A Scoping Review. Geriatrics (Basel). 2024 Jun 16;**9**(3):81. doi: 10.3390/geriatrics9030081. PMID: 38920437; PMCID: PMC11203250.
45 .De Giuseppe R, Colleoni M, Cremaschi M, Daconto L, Di Napoli I, Gallace A, et al. How to preserve healthy aging through nutritional strategies: The new approach of the Food Social Network (Food NET) project. Med J Nutrition Metab. 2022 Mar 9;**15**(1):91-101. https://doi.org/10.3233/mnm211500.
46. Gelmi G, Parisi G, Calloni L, Torri A, Capriulo AP, Celata C. Promuovere salute e prevenire cronicità nella popolazione over 65: il programma Gruppi di Cammino in Regione Lombardia. Psicologia della Salute. 2022;**3**:40-51. https://doi.org/10.3280/pds2022-003006.
47. Ippoliti R, Falavigna G, Grosso F, Maconi A, Randi L, Numico G. The Economic Impact of Clinical Research in an Italian Public Hospital: The Malignant Pleural Mesothelioma Case Study. Int J Health Policy Manag. 2018 Aug 1;**7**(8):728-737. https://doi.org/10.15171/ijhpm.2018.13. PMID: 30078293; PMCID: PMC6077275.
48. Longobucco Y, Benedetti C, Tagliaferri S, Angileri VV, Adorni E, Pessina M, et al. Proactive interception and care of Frailty and Multimorbidity in older persons: the experience of the European Innovation Partnership on Active and Healthy Ageing and the response of Parma Local Health Trust and Lab through European Projects. Acta Biomed. 2019 May 23;**90**(2):364-374. https://doi.org/10.23750/abm.v90i2.8419. PMID: 31125023; PMCID: PMC6776195.
49. Baldelli G, De Santi M, Masini A, Ridolfi E, Parenti A, Gobbi E, et al. Health-Related Quality of Life Improvement in Residential Care Facilities' Elders through a Physical Activity Program, Health & Social Care in the Community, 2023, 5584050. https://doi.org/10.1155/2023/5584050.
50. Age-It: Ageing Well in an Ageing Society. Available from: https://ageit.eu/wp/en/ [Last accessed: 2024 Oct 31].

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Lombardy Region: seven years of breast cancers screening before, during and after the SARS-CoV-2 pandemic

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Keywords: Screening Program; Cancer Prevention; Healthcare System organization
Parole chiave: Programmi di Screening; Prevenzione delle Neoplasie; Organizzazione dei Sistemi Sanitari

Abstract

Background. *Breast cancer represents the most common form of neoplasm in women, with an estimated 685,000 deaths annually. In this regard, screening programmes represent one of the most effective intervention tools in the field of cancer prevention. The aim of this study is to analyse and describe the key performance indicators of the screening programmes in Lombardy from 2016 to 2022.*
Study design. *Descriptive temporal analysis study.*
Methods. *The data pertaining to the screening campaign were subjected to analysis, with the results broken down according to the following criteria: individual province, age group eligible for screening, and campaign year. For each campaign, the data pertaining to the population subjected to screening, as well as the data concerning the rate of cancers identified during the campaign, were subjected to analysis.*
Results. *For the three age groups, a substantial overlap in call and campaign adherence rates can be observed, with stable values between 2016 and 2019, followed by a significant decline in the 2020 campaign associated with the impact of the pandemic on prevention activities, including cancer screening campaigns. The data for 2021 and 2022 indicate a reversal of the decline in adherence and call rates, particularly in the 45-49 age group, which exhibited an increase of approximately 300% in the call rate between 2021 and 2020. Moreover, the categorization of the provinces into urban, mountainous and rural provinces demonstrates an overlap in the admission rates between the three areas in the different years.*
Conclusions. *Despite the existence of mammography screening campaigns for more than 20 years, adherence rates in the Lombardy region remain below the targets set out in Europe's Beating Cancer Plan. In this regard, the observed variations, particularly during the period of the pandemic and in the subsequent post-pandemic period, provide an opportunity to rethink the organization of screening campaigns in order to increase adherence and effectiveness.*

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Introduction

Breast cancer is the most common type of cancer among women, causing 685,000 deaths globally (1,2). In Italy, it is liable for 12,500 deaths in 2021, with 55,700 recorded new cases in 2022 and 834,200 women living with the disease (3). Due to its prevalence, breast cancer is considered as one of the main public health and preventive medicine issues.

Screening programs are one of the most suitable and cost-effective intervention in public health and specifically in cancer prevention. Screening importance is underlined by several studies that found a decrease in mortality in countries that implemented organized population-based screening programs for early detection of the disease (4-12). Building on this and according to current evidence, the European Commission Initiative on Breast Cancer recommends the implementation of organized screening programs for women aged 45 to 49 (conditional recommendation, moderate certainty of the evidence), 50 to 69 (strong recommendation, moderate certainty of the evidence) and 70 to 74 (conditional recommendation, moderate certainty of the evidence), through digital mammography or tomosynthesis (13).

In 2020, European Union (EU), in order to cut down breast cancer mortality rate, placed a focus on the objectives of cancer screening programs through the Europe's Beating Cancer Plan. The objectives were to reach at least 90% coverage of the eligible population. Despite this ambitious objective and several implementation policies, such as the introduction of population-based breast cancer screening programs in 25 out of the 27 EU member state, coverage levels were still below the goal, ranging from 6% to 90% (14). The importance of screening and of a preventive approach to breast cancer is further highlighted by a study published in 2020 that estimated the decreasing of 12,434 breast cancer deaths in Europe by reaching a screening coverage rate of 100% (9).

In Italy each region is in charge for the implementation of screening programs according to national guidelines, guaranteeing a mammography every two years for women aged 50-69, with the possibility for each region to further extend the target population (15). In particular, Lombardy region has been implementing breast cancer screening since the early 2000s. In 2017 the target population has been extended to women aged 45-49 with annual mammography and to women aged 70-74 with a mammography every two years (16). The whole screening procedure is voluntary and has no cost for the citizens, aiming to provide equal access to care for all women

Screening programs can only function within a well-organized healthcare system, due to their considerable logistic costs and longtime results. This is one of the reasons why in specific situations, such as pandemic, the goal to guarantee primary care service could led to a temporary screening service outage. Notably, Lombardy region has been one of the first European areas to be invested by the COVID-19 pandemic in early 2020, resulting in a national lockdown which has severely impacted prevention and screening, with an important decrease in the number of invitations to mammography in 2020 (17,18).

The aim of this paper is to describe key performance indicators (KPIs) of the Lombardy regional breast cancer screening program from 2016 to 2022, a period which also includes the program delay due to the pandemic and eventually the resumption in 2022.

Materials and methods

Lombardy breast-cancer screening program setting

The national healthcare service operates in the territory of Lombardy region through eight local Health Protection Agencies (ATS) led by the Directorate-General Welfare. Each ATS is responsible for the management of the breast-cancer screening program in its area. Within the target population, individuals eligible to participate in the screening program are identified by excluding those who had a recent mammography (temporary suspension) or with diagnosis of breast cancer (permanent suspension). Eligible women receive a letter of invitation containing general information about the screening program and an appointment to perform the exam, which consists of a mammogram in two projections, independently reviewed by two radiologists. In the case of suspicious or positive results, the woman is referred for further diagnostic examinations. In the case of a negative result instead, the women re-enter the program and will be contacted again after two years (women aged 50-74) or one year (women aged 45-49).

Source of data and analysis

The Directorate-General Welfare yearly collects and analyzes data from each ATS through the form to be delivered to the Health Ministry through the National Screening Observatory. One ATS could not deliver complete cancer data for 2022 due to a hacker attack to the screening registry. The hacker attack

seriously corrupted the screening database, for year 2022 and before. Data about screening tests performed was almost rescued, whilst data about lesions detected was poorly restored. Data from 2016 to 2022 were collected in a datasheet on SAS Analytics Software 9.4. A preliminary analysis was performed to assess the viability of the survey's answers, searching for missing data or errors. Descriptive analysis were conducted analyzing categorical data as absolute frequencies and percentages. No inferentional analysis was conducted.

Key performance indicators

The following KPIs were analyzed for women aged 45-49, 50-69 and 70-74, for the years 2016-2022:

- adjusted invitation coverage: percentage of individuals invited to screening during the analysed period, compared to the target population, excluding undelivered invitations and individuals with specific exclusion criteria;
- examination coverage: percentage of individuals who underwent the examination compared to the target population, excluding individuals with specific exclusion criteria;
- recall rate (RR): the number of individuals recalled for further assessments as a proportion of all individuals who underwent a screening examination;
- detection rate (DR): the number of all malignant cancers detected every 1,000 screened individuals;
- positive predictive value (PPV): the ratio of lesions that are diagnosed as truly positive to those that test positive at the screening exam

The ATS were eventually clustered according to population and healthcare network difference. The three main ATS of Lombardy, Milano, Bergamo and Brescia were considered as city area, while the north area, corresponding to Varese and Sondrio, was considered as mountain area. The remaining ATSs were merged into countryside area.

Results

Table 1 presents data for the 50-69 age cohorts evaluated between 2016 and 2022. Adjusted invitation coverage was constantly around 100%, with the exception of the pandemic biennium when it dropped to 57.5 % (2020) and 84.3% (2021). Regarding the examination coverage, around half of the target population was covered by screening test in the organized program before the pandemic, whilst in 2020 only one out of three women was covered with the mammography. In terms of RR, the average is 10.4% for initial examinations and 4.4% for subsequent examinations. The PPV is approximately 4.4% for initial examinations and 9.4% for subsequent examinations. DR is between 3.9% and 4.9% for first examinations and between 4.0% and 4.5%. for subsequent examinations; the DR below 4.0%

Table 1 - Key performance indicators of Lombardy region breast-cancer screening program, 2016-2022, age group 50-69 years old.

	2016	2017	2018	2019	2020	2021	2022
Target population (n)	700,096	688,828	691,561	695,907	705,152	711,143	720,873
N. of invited subjects	624,502	611,981	652,557	649,903	375,884	563,653	696,303
Adjusted invitation coverage (%)	98.9	99.7	106.0	100.5	57.7	84.3	101.0
Examination coverage (%)	50.4	52.9	52.9	53.4	29.0	53.0	48.3
N. of screened women	352,566	364,139	365,684	371,357	204,750	376,926	347,879
Adjusted partecipation rate (%)	64.6	67.2	63.7	67.0	62.1	70.8	54.8
Recall rate (%)							
First screening	11.4	10.7	10.3	10.7	9.5	10.5	9.9
Subsequent	4.7	4.2	4.3	4.3	4.5	4.6	4.4
N. of screen-detected cancers	1,469	1,588	1,682	1,535	830	1,688	1,156
Detection rate (‰)							
First screening	4.9	4.9	5.0	4.8	3.9	4.2	3.5
Subsequent	4.0	4.3	4.5	4.0	4.1	4.5	3.3
Positive predictive value (%)							
First screening	4.5	4.7	5.0	4.6	4.2	4.4	3.7
Subsequent	8.8	10.2	10.6	9.6	9.2	9.9	7.5

observed in 2022 is probably due to the missing cancer cases registration in one ATS. Moreover, despite the impact of the SARS-CoV-2 pandemic, as evidenced by the reduced invitation rates, an analysis of clinical outcomes as detection rates revealed no substantial differences between the years preceding and those during the pandemic.

Table 2 presents data for the 70-74 cohorts evaluated from 2016 to 2022. Due to the gradual implementation of screening of screening extension for these cohorts by the Lombardy region, for 2016 and 2017 data are not available for all the ATS. The invitation coverage displays an increase followed by a drop, which can be attributed to the Sars-CoV-2 pandemic, and then a new increase. The examination coverage reaches 50% in 2018 and then is hampered as well by the pandemic. RR is similar to the one observed in the 50-69 age range; whilst DR and PPV are markedly higher in this age group: DR is higher than 8% in 2017-2018 and PPV is higher than 15% from 2017 on. In this regards, Table 2 illustrates that the 70-74 age group has been significantly affected by the impact of the SARS-CoV-2 pandemic on screening programmes. Indeed, the adjusted invitation coverage in 2020 is approximately half that observed in 2019, and the first screening detection rate in 2020 and 2021 is, respectively, approximately half and two-thirds of the 2019 rate.

Table 3 presents data for the 45-49 age cohorts evaluated from 2016 to 2022. As a consequence of the gradual implementation of screening extension for these cohorts by the Lombardy Region, data are not available for all ATSs for the years 2016, 2017, and 2018. The data demonstrate a notable variation in invitation coverage over time, with a consistent upward trajectory following the onset of the SARS-CoV-2 pandemic. Notably, the survey coverage has never exceeded 16% until 2021. The RR is comparable to that observed in both the 50-69 and 70-74 age groups, while the DR and PPV align with the values observed in the 50-69 cohorts.

In Figure 1 a breast screening participation rate is described according to the geographical area. Despite fluctuations we can note a substantial overlap among three areas with and increasing of response rate during 2021, with an average rise of 24.9%. In the same assessment we have also note an increasing of response range since 2020 during which the response rate between countryside and mountains was 8.6%, while the rage increase to 11.8% during 2021.

Discussion

Screening programs are among the most cost-effective strategies in medicine and they represent a cornerstone in prevention (19). Since its introduction, breast cancer screening has provided a fundamental preventive tool resulting in a decrease of mortality linked to this neoplasia (20). Italian National Healthcare Service (SSN) develops it through several

Table 2 - Key performance indicators of Lombardy region breast-cancer screening program, 2016-2022, age group 70-74 years old.

	2016*	2017**	2018	2019	2020	2021	2022
Target population (n)	35,770	85,565	135,827	140,895	144,787	149,080	146,434
N. of invited subjects	17,456	48,169	133,120	115,964	64,326	110,130	130,835
Adjusted invitation coverage (%)	53.2	59.3	109.2	92.0	47.8	81.5	95.4
Examination coverage (%)	34.1	33.0	53.0	49.3	24.4	49.3	48.5
N. of screened women	12,183	28,216	71,981	69,517	35,304	73,563	71,089
Adjusted partecipation rate (%)	81.0	68.1	61.4	69.9	62.5	70.2	58.4
Recall rate (%)							
First screening	9.2	10.9	10.1	11.1	7.6	11.6	8.8
Subsequent	5.2	5.0	4.6	4.6	4.1	4.5	4.5
N. of screen-detected cancers	58	240	649	517	244	583	707
Detection rate (‰)							
First screening	4.8	13.0	14.9	16.8	8.6	11.5	20.0
Subsequent	4.9	8.4	8.8	7.1	6.9	7.8	9.5
Positive predictive value (%)							
First screening	5.3	12.0	14.8	15.2	11.3	10.0	21.3
Subsequent	9.4	16.6	18.8	15.4	16.7	17.3	21.5

*For 2016, data is available only for two ATS, ** For 2017, data is available only for 6 ATS

Table 3 - Key performance indicators of Lombardy region breast-cancer screening program, 2016-2022, age group 45-49 years old

	2016*	2017**	2018***	2019	2020	2021	2022
Target population (n)	35,570	15,383	57,026	190,912	214,885	201,998	197,941
N. of invited subjects	7,073	971	1,201	57,852	50,731	72,956	177,646
Adjusted invitation coverage (%)	19.64	6.59	2.17	32.04	24.06	36.81	90.09
Examination coverage (%)	9.52	5.60	1.90	15.82	11.66	20.25	47.81
N. of screened women	3,385	861	1,082	30,199	25,060	40,896	94631
Adjusted partecipation rate (%)	59.6	91.1	92.9	62.5	56.3	61.6	58.7
Recall rate (%)							
First screening	3.3	12.3	10.3	11.4	11.3	11.8	11.3
Subsequent	9.5	7.5	4.9	7.5	7.5	6.8	6.4
N. of screen-detected cancers	13	3	5	106	68	122	274
Detection rate (‰)							
First screening	3.5	4.2	4.3	3.6	2.7	3.2	3.2
Subsequent	8.2	0	7.0	3.0	2.7	2.6	1.8
Positive predictive value (%)							
First screening	10.4	3.4	4.1	3.2	2.4	2.7	2.9
Subsequent	8.7	0	14.3	4.0	3.6	3.8	2.8

*For 2016, data are available only for two ATS, ** For 2017, data are available only for 6 ATS, *** For 2018, data are available only for 4 ATS

Regional Healthcare Services (SSR) involved in decision policies making such as screening age range. Our analysis has been performed on the experience of Lombardy SSR between 2016 and 2022 (21). Lombardy is the most populated Italian region with close to 10 million inhabitants and with the sixth lowest average age close to 46 years (22).

To assess the overall effectiveness of breast cancer screening programmes we focused on organizational and clinical results, such as the ratio of invited women, adherence and cancer diagnosis by stage. Firstly, we analyzed the invited patient ratio and their adherence to the screening program.

The analysis considered three population cohorts: 45-49, 50-69 and 70-74 years. The adjusted coverage showed a significant difference between the cohorts,

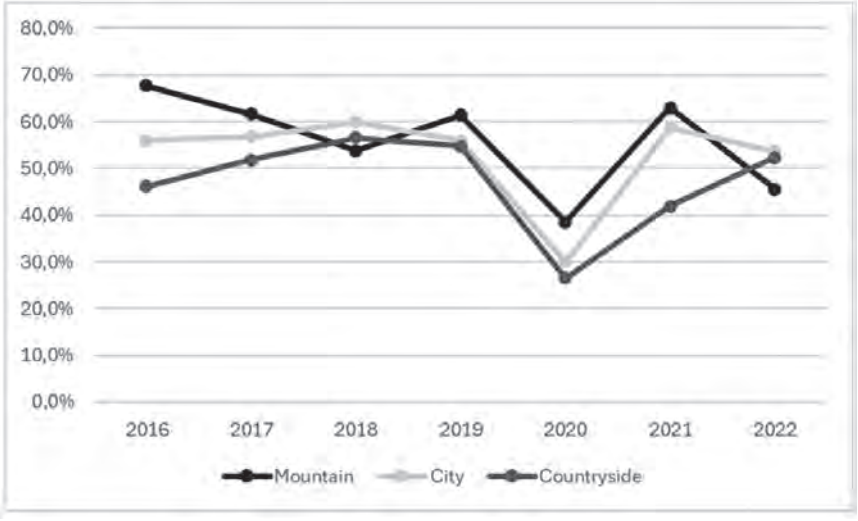

Figure 1 - Clusterized breast screening response rate in Lombardy region 2016-2022 (50-69 y.o. cohort)

which can be partly explained by the different timing of the screening programme introduction and partly by the age difference. Indeed, age is reported as a factor influencing adherence to cancer screening campaigns in the literature, with increased adherence in younger age groups.

e same time, the mean responder rate of close to 56% emphasizes a sore point, the screening test refusal or hesitancy. Indeed, despite the importance of screening programs to cut down the breast cancer mortality rate, different studies all around the world show a lower adherence to mammography screening (5,23-26). It's interesting to note that adherence increasing in 2021 overcoming the pre-pandemic level, as a response to COVID-19 and the disclosure about the importance of prevention.

In this context, the potential psychological impact of COVID-19 pandemic on public attention to preventive health measures may be a crucial factor in the observed increase in adherence to such measures. Indeed, some studies suggest that the pandemic has influenced the uptake of preventive health interventions (27-29). This evidence lends support to the hypothesis that the observed increase in adherence rates since 2021, which has resulted in even higher rates than during the pandemic period, may be attributable to a shift in perception towards viewing screening interventions as a crucial tool for protecting health.

In addition, the time-frame analysis has highlighted another interesting point; the COVID-19 pandemic has affected the screening program probably through the temporal disruption of the healthcare system schedule, but the adherence remained about the same, close to 55%, and below the average of the European high-income nations, even though screening age targets are different (30). Indeed, despite a dizzying fall of invitation ratio dropping from 90% to 53% which shows the consequence of the pandemic with the interruption of emergency and non-urgent paths of care, especially during the first month of the pandemic, data on temporary trend confirm a lower attention towards these preventive campaigns.

At the same time, in order to assess the influence of healthcare network and spreading among region, our team has performed a partition of Lombardy ATSs by reclassifying them into three areas based on population and healthcare network features.

This study is one of the first in the literature to identify the influence of the territory or the organization of a healthcare system on patient adherence to a screening campaign, rather than socio-economic factors. Notably, a greater range was observed in the years 2016, 2020, and 2021. The observed differences in adherence rates between the three areas, particularly in 2016 and 2021, could be attributed to the transition of the regional healthcare system in 2015. This involved the reorganization of territorial prevention networks and the resumption of cancer screening activities following the end of the COVID-19 pandemic. Regarding the resumption, the faster rise in rates in certain territorial areas may be due to the presence of large centres that performed most screening tests before the pandemic, compared to areas with a dense network of providers. Many patients may have delayed joining the campaign due to difficulties or complexities in reaching the test site. This is because screening services have been diverted to large hubs to ensure the provision of basic services in territorial networks.

Considering the diagnostic elements, the analysis has highlighted two elements. The first one is, as for the invitation, the effect of the COVID-19 pandemic on cancer detection rates. The comparison between invitation decreases (40.98%) and cancer detection decreases (46.38%) shows a difference close to 5%. Due to our experience and several studies performed on different cancer screening, such as cervical cancer, we can assumed that one potential explanation for this phenomenon is that women who adhere to a healthier lifestyle are also more careful about preventive health activities, including participation in cancer screening programmes (31,32). Moreover, the disruption of healthcare systems caused by the COVID-19 pandemic could have exacerbated this trend.

At the same time, the loss of data from the aforementioned ATS, although confined to one ATS and therefore not involving the entire Lombardy region, could offer an additional partial explanation for the diminished detection rate that was observed during the course of 2022. It is important to note that, despite the potential repercussions of the data loss, the reliability of the study's findings appears to remain unaffected. This observation is particularly salient in the context of the outcomes derived from regional screening initiatives. The only result of the study in which this issue has the potential to compromise the reliability pertains to the comparison between the countryside, the city and the mountains. This is due to the fact that the ATS damaged by the attack is predominantly present in one of these areas.

The second one is the decreased trend in benign neoplasms surgery, which could be partially explained by the advancement in diagnostic techniques and a change in the approach towards benign lesions (33).

This approach has changed radically the view of breast cancer interventions and increased the necessity of early diagnosis, underlining the importance of breast cancer screening. Indeed, despite a higher identification rate increasing the incidence of breast cancer, implementing organized population-based screening programs could lead to early detection of malignancy in its first stage, therefore, decreasing mortality as described in several studies (34-40).

Limitations

Cancer screening is one of the most important instruments in preventive medicine and its importance is underlined by the malignancy detection rate that supports early operations to avoid cancer evolution and mortality. Despite more than 20 years of breast cancer screening programs, the adherence in Lombardy region remains low, under 60%. On this regard a study that tried to provide a comprehensive analysis on screening program data and potential explanation for its variation represents a cornerstone. The main limitation of this study is the absence of literature to support this reading framework about the psychological influence of COVID-19 on adhesion. The second one is the short-term follow-up based only on 2021 data that may not reflect a real mindset change but only a specific timeframe due for instance tothe 2020 examination skipping. So, this original article could be considered as a first step to a more extensive analysis that could be considered a post-pandemic long-term follow-up to assess the change in breast screening program organization and adherence.

Conclusions

Despite the effects of the COVID-19 pandemic on the healthcare system and the temporary disruption of screening programs, screening program empowerment is essential to provide a widespread organization. The pandemic affects not only the organization and the functions of the healthcare systems, but also the adhesion: in other words, it can begin to show an increase compared to the pre-pandemic percentage.

The rise of post-pandemics adherence calls attention to the fact that during the pandemic the avoidance or delay in accepting the screening practices is probably caused by fear or discomfort; the following reaction to such sentiments could be used to increase screening programs participation and, in a longer run, to radically rethink the organization.

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Riassunto

Regione Lombardia: sette anni di screening del cancro al seno prima, durante e dopo la pandemia di SARS-CoV-2

Background. Il tumore mammario rappresenta la tipologia di neoplasia più frequente nel genere femminile responsabile di 685.000 morti ogni anno. I programmi di screening rappresentano a tal proposito uno degli strumenti di intervento più efficaci in ambito di prevenzione neoplastica. Scopo dello studio è quindi quello di analizzare e descrive i key performance indicators (KPIs) dei programmi di screening lombardi dal 2016 al 2022.

Disegno dello studio. Studio descrittivo di analisi temporale.

Metodi. Sono stati analizzati i dati relativi alle campagne di screening suddivisi per singola provincia, per fascia di età convocata per lo screening e per anno di campagna. Per ogni campagna sono stati analizzati dati relativi alla popolazione soggetta a screening e dati relativi al tasso di cancri identificati nel corso della campagna.

Risultati. Per le tre fasce di età si può osservare una sostanziale sovrapposizione di tasi di chiamata e di adesione alle campagne, con valori stabili tra il 2016 e il 2019, seguiti da un'importante diminuzione nella campagna 2020 associabile all'impatto che il covid ha avuto sulle attività di prevenzione come campagne di screening oncologico. I dati del 2021 e 2022 mostrano una ripresa di adesione e di chiamata, in particolare nella fascia di età 45-49 anni, che mostra un incremento di circa il 300% del tasso di chiamata tra il 2021 e il 2020. Inoltre, la classificazione delle provincie in province urbane, montuose e rurali mostra una sovrapposizione dei tassi di adesione tra le tre aree nei vari anni.

Conclusioni. Nonostante l'esistenza di campagne di screening mammografica da oltre 20 anni i tassi di adesione in regione Lombardia rimangono al di sotto degli obiettivi dello Europe's Beating Cancer Plan. A tal proposito, le variazioni osservati in particolare in occasione della pandemia da Covid-19 e nel periodo post pandemico rappresentano un elemento da cui partire, ripensando l'organizzazione delle campagne di screening, per aumentare l'adesione ed efficacia.

References

1. World Health Organization (WHO). Breast Cancer [Internet]. 2021. Available from: https://www.who.int/news-room/

fact-sheets/detail/breast-cancer [Last accessed: 2024 Nov 14].
2. Wilkinson L, Gathani T. Understanding breast cancer as a global health concern. Br J Radiol. 2022 Feb 1;**95**(1130):20211033. doi: 10.1259/bjr.20211033. Epub 2021 Dec 14. PMID: 34905391; PMCID: PMC8822551.
3. Associazione Italiana di Oncologia Medica (AIOM), Associazione Italiana Registri Tumori (AIRT), Fondazione AIOM, Osservatorio Nazionale Screening (ONS), PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia), et al. I numeri del cancro in Italia. 2022.
4. Lauby-Secretan B, Scoccianti C, Loomis D, Benbrahim-Tallaa L, Bouvard V, Bianchini F, et al. Breast-Cancer Screening-Viewpoint of the IARC Working Group. N Engl J Med. 2015 Jun 11;**24**(372):2353-8. doi: 10.1056/NEJMsr1504363. Epub 2015 Jun 3. PMID: 26039523.
5. Coldman A, Phillips N, Wilson C, Decker K, Chiarelli AM, Brisson J, et al. Pan-Canadian study of mammography screening and mortality from breast cancer. J Natl Cancer Inst. 2014 Oct 1;**106**(11):261. doi: 10.1093/jnci/dju261. PMID: 25274578.
6. Australian Institute of Health and Welfare. BreastScreen Australia monitoring report 2008-2009. Canberra: Australian Institute of Health and Welfare; 2011.
7. Youlden DR, Cramb SM, Dunn NA, Muller JM, Pyke CM, Baade PD. The descriptive epidemiology of female breast cancer: an international comparison of screening, incidence, survival and mortality. Cancer Epidemiol. 2012 Jun;**36**(3):237-48. doi: 10.1016/j.canep.2012.02.007. Epub 2012 Mar 27. PMID: 22459198.
8. Njor S, Nyström L, Moss S, Paci E, Broeders M, Segnan N, et al. Breast cancer mortality in mammographic screening in Europe: A review of incidence-based mortality studies. J Med Screen. 2012 Sep;**19**(Suppl 1):33-41. doi: 10.1258/jms.2012.012080. PMID: 22972809.
9. Zielonke N, Kregting LM, Heijnsdijk EAM, Veerus P, Heinävaara S, McKee M, de Kok IMCM, et al. The potential of breast cancer screening in Europe. Int J Cancer. 2021 Jan 15;**148**(2):406-18. doi: 10.1002/ijc.33204. Epub 2020 Jul 30. PMID: 32683673; PMCID: PMC7754503.
10. Marmot MG, Altman DG, Cameron DA, Dewar JA, Thompson SG, Wilcox M. The benefits and harms of breast cancer screening: an independent review. Br J Cancer. 2013 Jun 11;**108**(11):2205-40. doi: 10.1038/bjc.2013.177. Epub 2013 Jun 6. PMID: 23744281; PMCID: PMC3693450.
11. National Healthcare System (NHS). NHS population screening: access and order leaflets [Internet]. 2018. Available from: https://www.gov.uk/guidance/how-to-order-population-screening-leaflets [Last accessed: 2024 Nov 14].
12. National Healthcare System (NHS). Breast screening: programme overview [Internet]. 2015. Available from: https://www.gov.uk/guidance/breast-screening-programme-overview [Last accessed: 2024 Nov 14].
13. European Commission. Screening ages and frequencies [Internet]. 2023. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cancer_screening_statistics [Last accessed: 2024 Nov 14].
14. Group of Chief Scientific Advisors, European Commission, Directorate-General for Research and Innovation. Cancer screening in the European Union Independent Expert Report [Internet]. Brussels; 2022.
15. Repubblica Italiana. Decreto del Presidente del Consiglio dei Ministri 12 gennaio 2017. Definizione e aggiornamento dei livelli essenziali di assistenza, di cui all'articolo 1, comma 7, del decreto legislativo 30 dicembre 1992, n. 502. GU Serie Generale n. 65 del 18 marzo 2017 (Suppl Ord n. 15). Available from: https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2017-03-18&atto.codiceRedazionale=17A02015&elenco30giorni=false [Last accessed: 2024 Nov 14].
16. Regione Lombardia. Decreto della Direzione Generale Welfare 3 aprile 2017, n. 3711. Aggiornamento fasce eta' target dei programmi di screening oncologici per la prevenzione del tumore della mammella e del colon retto. Available from: https://www.regione.lombardia.it/wps/portal/istituzionale/HP/DettaglioServizio/servizi-e-informazioni/enti-e-operatori/sistema-welfare/promozione-della-salute/screening-prevenzione-tumori/ddg2017-3711-aggiornamento-fasce-eta-screening [Last accessed: 2024 Nov 14].
17. Battisti F, Falini P, Gorini G, Sassoli de Bianchi P, Armaroli P, Giubilato P, et al. Cancer screening programmes in Italy during the COVID-19 pandemic: an update of a nationwide survey on activity volumes and delayed diagnoses. Ann Ist Super Sanita. 2022 Jan-Mar;**58**(1):16-24. doi: 10.4415/ANN_22_01_03. PMID: 35324470.
18. Battisti F, Mantellini P, Falini P, Ventura L, Giordano L, Saguatti G, et al. Key performance indicators of breast cancer screening programmes in Italy, 2011-2019. Ann Ist Super Sanita. 2022 Oct-Dec;**58**(4):244-253. doi: 10.4415/ANN_22_04_04. PMID: 36511195.
19. Iragorri N, Spackman E. Assessing the value of screening tools: reviewing the challenges and opportunities of cost-effectiveness analysis. Public Health Rev. 2018 Jul 13;39:17. doi: 10.1186/s40985-018-0093-8. PMID: 30009081; PMCID: PMC6043991.
20. Ministero della Salute. Screening per il cancro del seno [Internet]. 2023. Available from: https://www.salute.gov.it/portale/tumori/dettaglioContenutiTumori.jsp?lingua=italiano&id=5542&area=tumori&menu=screening [Last accessed: 2024 Nov 14].
21. Regione Lombardia. Legge Regionale 30 dicembre 2009, n. 33. Testo unico delle leggi regionali in materia di sanità. BURL n. 52 del 31 dicembre 2009 (3° Suppl Ord). Available from: https://normelombardia.consiglio.regione.lombardia.it/normelombardia/Accessibile/main.aspx?iddoc=lr002009123000033&view=showdoc [Last accessed: 2024 Nov 14].
22. Istituto Nazionale di Statistica (ISTAT). 2023. Indicatori Demografici. Available from: http://dati.istat.it/Index.aspx?DataSetCode=DCIS_INDDEMOG1# [Last accessed: 2024 Nov 14].
23. Australian Institute of Health and Welfare. Breast Screen Australia monitoring report 2006-2007 and 2007-2008

(full publication; 21/7/2010 edition); 2006. Available from: https://www.aihw.gov.au/getmedia/3a4594c3-1a9b-4fcb-9-d1b-5be1eeaa9011/11751.pdf?v=20230605165037&inline=true [Last accessed: 2024 Nov 14].
24. Loewen OK, Sandila N, Shen-Tu G, Vena JE, Yang H, Patterson K, et al. Patterns and predictors of adherence to breast cancer screening recommendations in Alberta's Tomorrow Project. Prev Med Rep. 2022 Nov 15; **30**:102056. doi: 10.1016/j.pmedr.2022.102056. PMID: 36531110; PMCID: PMC9747638.
25. Israel Cancer Association (ICA). Breast Cancer [Internet]. 2021. Available from: https://en.cancer.org.il/template_e/default.aspx?PageId=7749 [Last accessed: 2024 Nov 14].
26. Genovese C, Squeri R, Alessi V, Conti A, D'Amato S, Mazzitelli F, et al. Adherence to the three Italian screening in a sample of women (and men) in the Southern Italy. Clin Ter. 2021 Jan 1;**172**(1):e75-e79. doi: 10.7417/CT.2021.2287. PMID: 33346333.
27. Sarkar S, Kaur T, Ranjan P, Sahu A, Kumari A. Tools for the evaluation of the psychological impact of COVID-19: A practical guide for Family physicians and Primary Care Practitioners. J Family Med Prim Care. 2021 Apr;**10**(4):1503-1507. doi: 10.4103/jfmpc.jfmpc_2107_20. Epub 2021 Apr 29. PMID: 34123881; PMCID: PMC8144778.
28. Agorastos A, Tsamakis K, Solmi M, Correll CU, Bozikas VP. The need for holistic, longitudinal and comparable, real-time assessment of the emotional, behavioral and societal impact of the COVID-19 pandemic across nations. Psychiatriki. 2021 Apr 19;**32**(1):15-18. English, Greek, Modern. doi: 10.22365/jpsych.2021.010. Epub 2021 Mar 8. PMID: 33759804.
29. Perrone PM, Biganzoli G, Lecce M, Campagnoli EM, Castrofino A, Cinnirella A, et al. Influenza Vaccination Campaign during the COVID-19 Pandemic: The Experience of a Research and Teaching Hospital in Milan. Int J Environ Res Public Health. 2021 May 30;**18**(11):5874. doi: 10.3390/ijerph18115874. PMID: 34070763; PMCID: PMC8198860.
30. Altobelli E, Rapacchietta L, Angeletti PM, Barbante L, Profeta FV, Fagnano R. Breast cancer screening programmes across the WHO European region: Differences among countries based on national income level. Int J Environ Res Public Health. 2017 Apr 23;**14**(4):452. doi: 10.3390/ijerph14040452. PMID: 28441745; PMCID: PMC5409652.
31. Petkeviciene J, Ivanauskiene R, Klumbiene J. Sociodemographic and lifestyle determinants of non-attendance for cervical cancer screening in Lithuania, 2006–2014. Public Health. 2018 Mar;**156**:79-86. doi: 10.1016/j.puhe.2017.12.014. Epub 2018 Feb 3. PMID: 29408192.
32. Richard A, Rohrmann S, Schmid SM, Tirri BF, Huang DJ, Güth U, et al. Lifestyle and health-related predictors of cervical cancer screening attendance in a Swiss population-based study. Cancer Epidemiol. 2015 Dec 1;**39**(6):870-6. doi: 10.1016/j.canep.2015.09.009. Epub 2015 Nov 9. PMID: 26651449.
33. Kumar P, Kumar S, Baruah CC. Breast cancer management. Biomed Pharmacother. 2013 Oct;**67**(8):685-6. doi: 10.1016/j.biopha.2013.06.010. Epub 2013 Jul 10. PMID: 23906758.
34. Welch HG, Prorok PC, O'Malley AJ, Kramer BS. Breast-Cancer Tumor Size, Overdiagnosis, and Mammography Screening Effectiveness. N Engl J Med. 2016 Oct 13;**375**(15):1438-1447. doi: 10.1056/NEJMoa1600249. PMID: 27732805.
35. Møller MH, Lousdal ML, Kristiansen IS, Støvring H. Effect of organized mammography screening on breast cancer mortality: A population-based cohort study in Norway. Int J Cancer. 2019 Feb 15;**144**(4):697-706. doi: 10.1002/ijc.31832. Epub 2018 Oct 22. PMID: 30144028.
36. Niell BL, Freer PE, Weinfurtner RJ, Arleo EK, Drukteinis JS. Screening for Breast Cancer. Radiol Clin North Am. 2017 Nov;**55**(6):1145-1162. doi: 10.1016/j.rcl.2017.06.004. PMID: 28991557.
37. Monticciolo DL, Newell MS, Moy L, Niell B, Monsees B, Sickles EA. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. J Am Coll Radiol. 2018 Mar;**15**(3 Pt A):408-414. doi: 10.1016/j.jacr.2017.11.034. Epub 2018 Jan 19. PMID: 29371086.
38. Cooper K, Siefert A, Weinreb J. Skills Beyond the Reading Room: Training in Innovation and Collaboration at a Radiology Hackathon. J Am Coll Radiol. 2018 Mar;**15**(3 Pt A):466-468. doi: 10.1016/j.jacr.2017.11.034. Epub 2018 Jan 19. PMID: 29371086.
39. Guiberteau MJ, Oates ME. Counterpoint: Nuclear Medicine's Decline: Radiology Is the Solution, Not the Problem. J Am Coll Radiol. 2018 Mar;**15**(3 Pt A):387-389. doi: 10.1016/j.jacr.2017.11.029. PMID: 29502650.
40. Kovacs MD, Sheafor DH, Thacker PG, Hardie AD, Costello P. Metrix Matrix: A Cloud-Based System for Tracking Non-Relative Value Unit Value-Added Work Metrics. J Am Coll Radiol. 2018 Mar;**15**(3 Pt A):415-421. doi: 10.1016/j.jacr.2017.10.028. Epub 2017 Dec 24. PMID: 29279292.

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Knowledge and perception of modern learning approaches in Continuing Medical Education: a cross-sectional study

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Keywords: Continuing Medical Education; Engagement; Active Learning; Simulation; Role-playing; Gamification
Parole chiave: Educazione Continua in medicina; Engagement; Apprendimento attivo; Simulazione; Role-playing; Ludicizzazione

Abstract

***Background**. Continuing Medical Education (CME) is essential for enhancing professional performance. Modern CME approaches should prioritize adaptability and engagement through interactive and experiential learning, fostering better knowledge retention, skill application, and innovation to meet evolving healthcare challenges. This study aims to assess knowledge and perceptions of perceived role of engagement and active learning techniques in CME in the Italian population.*
***Methods.** We conducted a pilot study with cross-sectional design among graduate and post-graduate students from the University of Modena and Reggio Emilia in 2023, by administering a 17-item questionnaire about knowledge, and perceptions of CME.*
***Results.** We included 43 participants (median age 25, 72% females). Role of CME was recognized by 72.1%, and 53.5% were aware of its benefits. Likert responses showed high perceived importance of CME and engagement (mean scores 3.79 and 4.40). Active approaches like simulation (68.3%) and role-playing (65.9%) were familiar, but gamification (36.6%) was far less known.*
***Conclusions.** While methods like simulation, role-playing, case-based learning, and problem-based learning were familiar to study participants for their strong evidence of effectiveness, emerging approaches such as gamification and team-based learning were less known. Such approaches require further implementation in educational programs to show their benefits.*

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Introduction

Within a rapidly evolving scientific knowledge, including (and particularly) that related to human medicine, it is mandatory that healthcare workers maintain and develop their professional competences. The rapid pace of technological advancements and healthcare challenges further underscores the need for adaptive continuous education to ensure high standards of care and innovation within healthcare systems (1-5). Lifelong learning and Continuing Medical Education (CME) are therefore pivotal in the modern healthcare sector, as they ensure the ongoing development of healthcare professionals' skills and knowledge for improving the quality of healthcare services (6-8). CME is defined as "*educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession*" (9,10) and is rooted in the principle that healthcare professionals must be regularly updated on the latest scientific and technological knowledge to provide high-quality, evidence-based care (6,11).

In Italy, the CME has been recognized as mandatory for all health professionals 1992, following the Legislative Decree no. 502. This and the following regulatory framework, Legislative Decree no. 229/1999, made CME a consistent and uniform process across the country integrating national, regional, and organizational levels, supporting the harmonization of healthcare services (12). CME includes a variety of formats—classroom, online, and in-person training—aimed at enhancing clinical, technical, and managerial skills (13). In particular, modern learning approaches prioritize flexibility and dynamism over traditional, static education methods, encouraging healthcare organizations to become learning organizations (14,15). These approaches foster the exchange of knowledge and experiences, allowing professionals to build practical expertise alongside academic knowledge; experiential learning and reflection are crucial for developing critical thinking and problem-solving abilities in real-world scenarios (16). Recent research shows that interactive CME approaches, such as learning by doing, peer learning, and analyzing past incidents, are more effective than traditional lectures, improving both knowledge and clinical practice (17). In particular, they demonstrated to improve healthcare outcomes not only by preventing errors, but also by enhancing innovation within the organization (13,14,18,19).

Despite the benefits of modern education approaches especially for the healthcare providers, the knowledge about available approaches methods, their role and use in biomedical education have not been explored. For these reasons, this study aims to assess the perceived role of engagement and active learning techniques in CME in order to expand the current literature on the topic and highlight the importance of these critical aspects of CME.

Methods

We conducted a cross-sectional study involving a sample of the graduate and post-graduate students from University of Modena and Reggio Emilia, Northern Italy. The inclusion criteria were being adults (≥18 years), having Italian as native language, and being students attending (graduate) or having attended (post-graduate) Public Health courses.

With the help of co-authors expert in didactics, pedagogy, and e-learning, we designed a questionnaire of 17 mixed-type questions to collect socio-demographic information, including educational attainment and occupation, and to investigate the participants knowledge and the perceived relevance of CME using a Likert scale ranging from 1 ("low") to 5 ("high") (Supplementary Material).

The questionnaire was designed for self-administration and online completion. We made available online the questionnaire from May to November 2023 and collected data electronically via Google Forms. We performed analysis using the Software IBM SPSS Statistics Version 29.0.0.0. We then analyzed the collected data, to assess the sociodemographic characteristics of participants and their responses to the questionnaire using descriptive statistics, including frequencies, percentages, means, and standard deviations. We conducted a reliability analysis of the Likert-scale items related to CME and engagement in order to assess their internal consistency using Cronbach's alpha test. We used Chi-square tests to explore relations between categorical variables and dichotomous survey responses. We used Microsoft Excel (Office Package, Microsoft Corp., Redmond, WA, 2024) for data visualization. We conducted the study according to the Declaration of Helsinki. Approval from the Ethics Committee was waived due to the use of entirely anonymous and aggregated data hampering personal identification of participants (20).

Results

Forty-three individuals participated in the study, with a response rate of 45.2%. Table 1 outlines their main sociodemographic characteristics. Participants had a median age of 25 years and were mainly females (72.1%). High school's degree (44.2%) and bachelor's degree (27.9%) were the most frequent educational attainment levels. As regards occupational status, participants were mainly working post-graduate students (55.8%) following by graduate students (44.2%).

Knowledge of CME meaning was high among participants (72.1%), while CME benefits and purposes were clear for 53.5% only. Forty participants (93.0%) believed digital technologies to be useful to rise education engagement, and the almost all of them (97.7%) believed innovative strategies to be useful to rise education engagement. All participants considered that personalized learning to be useful in the healthcare sector.

As shown in Figure 1, CME approaches familiar in the study participants were: increase in interest (53.5%) and development of practical skills (58.1%);

Table 1 - Characteristics of the study sample (N=43). Values expressed as N (%) if not differently reported.

Characteristics	N (%)
Age (years)	
Median (IQR)	25 (23-37)
18-25	25 (58.1)
26-35	7 (16.3)
>35	11 (25.6)
Gender	N (%)
Male	12 (27.9)
Female	31 (72.1)
Educational attainment	
High school	19 (44.2)
Bachelor's degree	12 (27.9)
Post-graduate degree*	12 (27.9)
Occupational status	
Working student	24 (55.8)
Student	19 (44.2)

* *Master's degree, PhD,* Level 5B ISCED (International Standard Classification of Education), Postgraduate Master's degree (first cycle).

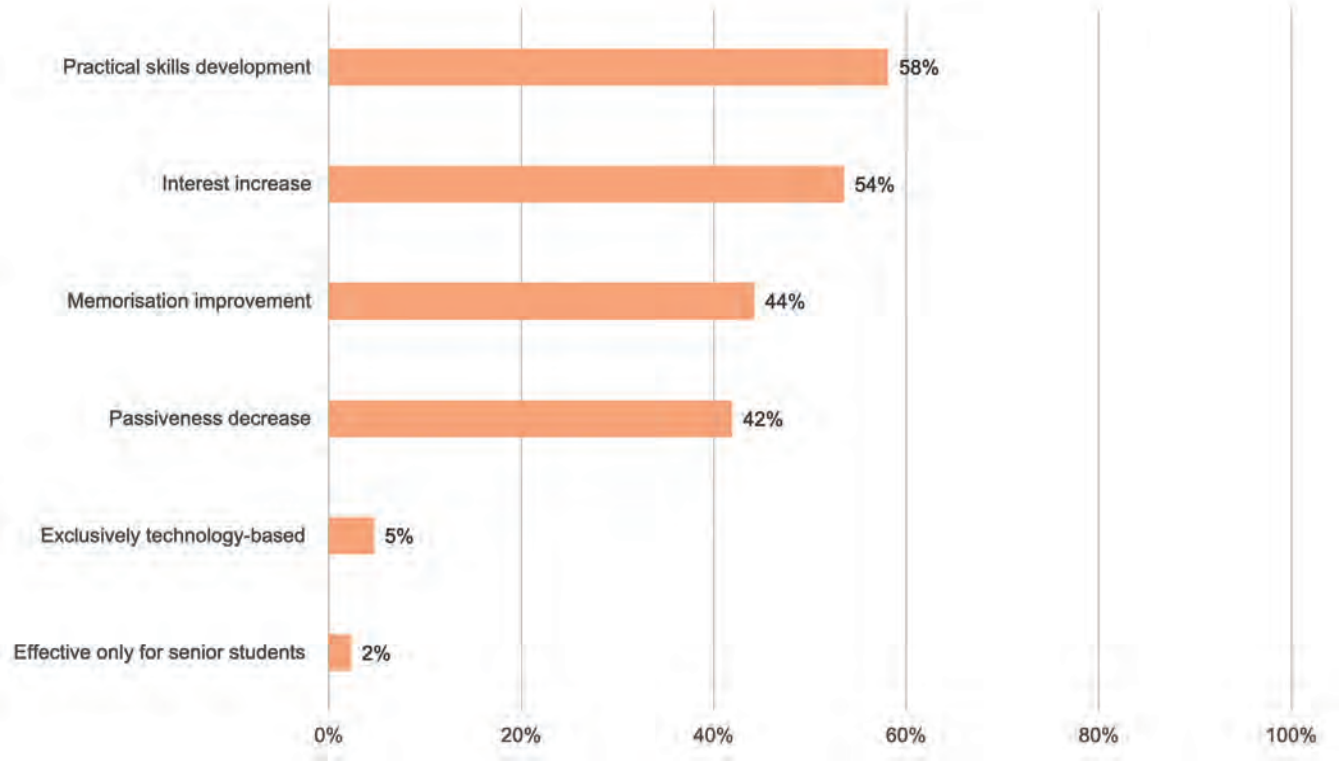


Figure 1. Familiar and unfamiliar approaches to increase engagement in education.

whereas the less familiar were: exclusively technology-based (4.7%) and effective only for senior students (2.3%).

Figure 2 shows the distribution of knowledge about active approaches to increase engagement, with percentages over 60% for simulation, role-playing, case-based learning, and problem-based learning, while the less familiar active approach was gamification (36.6%).

Answers to Likert survey questions are shown in Figure 3. On a scale from 1 to 5 where 1 was "low" and 5 was "high", the rating about the impact

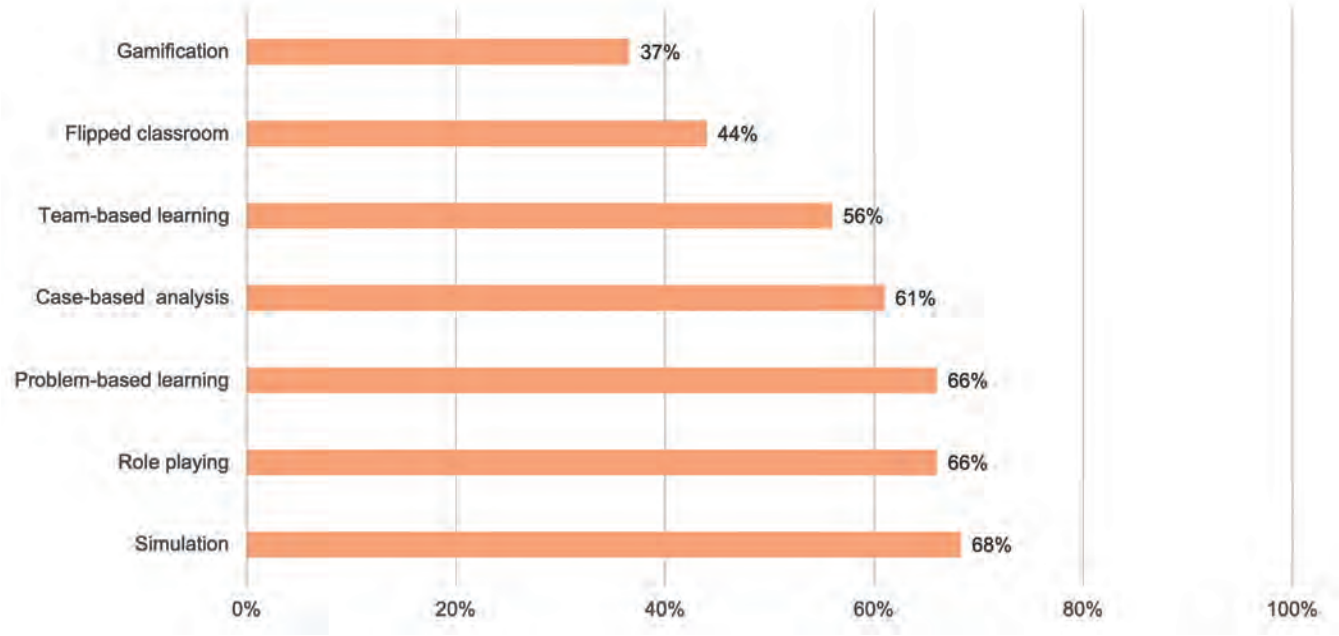


Figure 2. Distribution of knowledge of active learning approaches to increase engagement in the study sample.

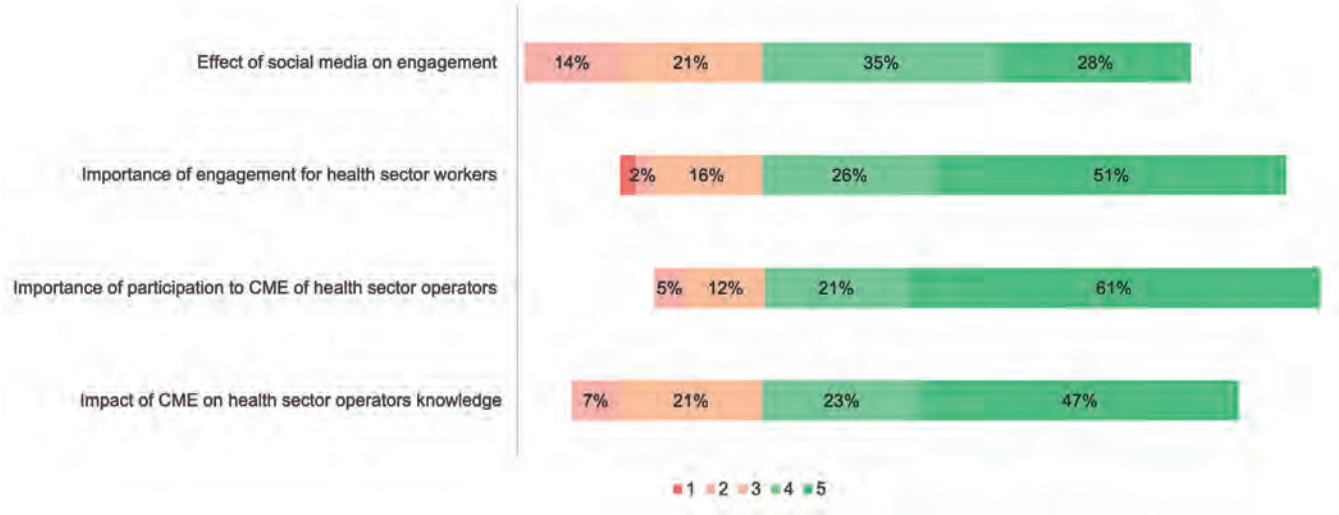


Figure 3. Answers to Likert questions. Scale ranges from 1 ("low") and 5 ("high").

of CME, the importance of participation to CME, and the importance of engagement for healthcare professionals are very high, with mean values of 4.12 (SD 0.99), 4.40 (SD 0.88), and 4.24 (SD 0.98), respectively. Slightly lower values can be noted when assessing the effect of social media on engagement (mean value: 3.79, SD 1.02).

The reliability analysis to assess internal consistency on the four items related to the impact of CME and engagement in the healthcare sector was conducted using Cronbach's alpha, with a value of 0.814, indicating strong reliability, with contribution from all items. In particular, the item "Importance attributed to the participation in CME by healthcare personnel" showed the highest corrected item-total correlation (r = 0.814) and contributed most strongly to the internal consistency of the scale. Exclusion of this item would decrease the Cronbach's alpha to a value of 0.686.

No major differences between the categorical variables. The Chi-square tests were conducted to examine the relation between various categorical variables (gender, educational attainment, and occupational status) and dichotomous questions such as perceived meaning of CME, its benefits and purposes, digital technology, personalized learning and innovative strategies usefulness (Figure 4).

Discussion

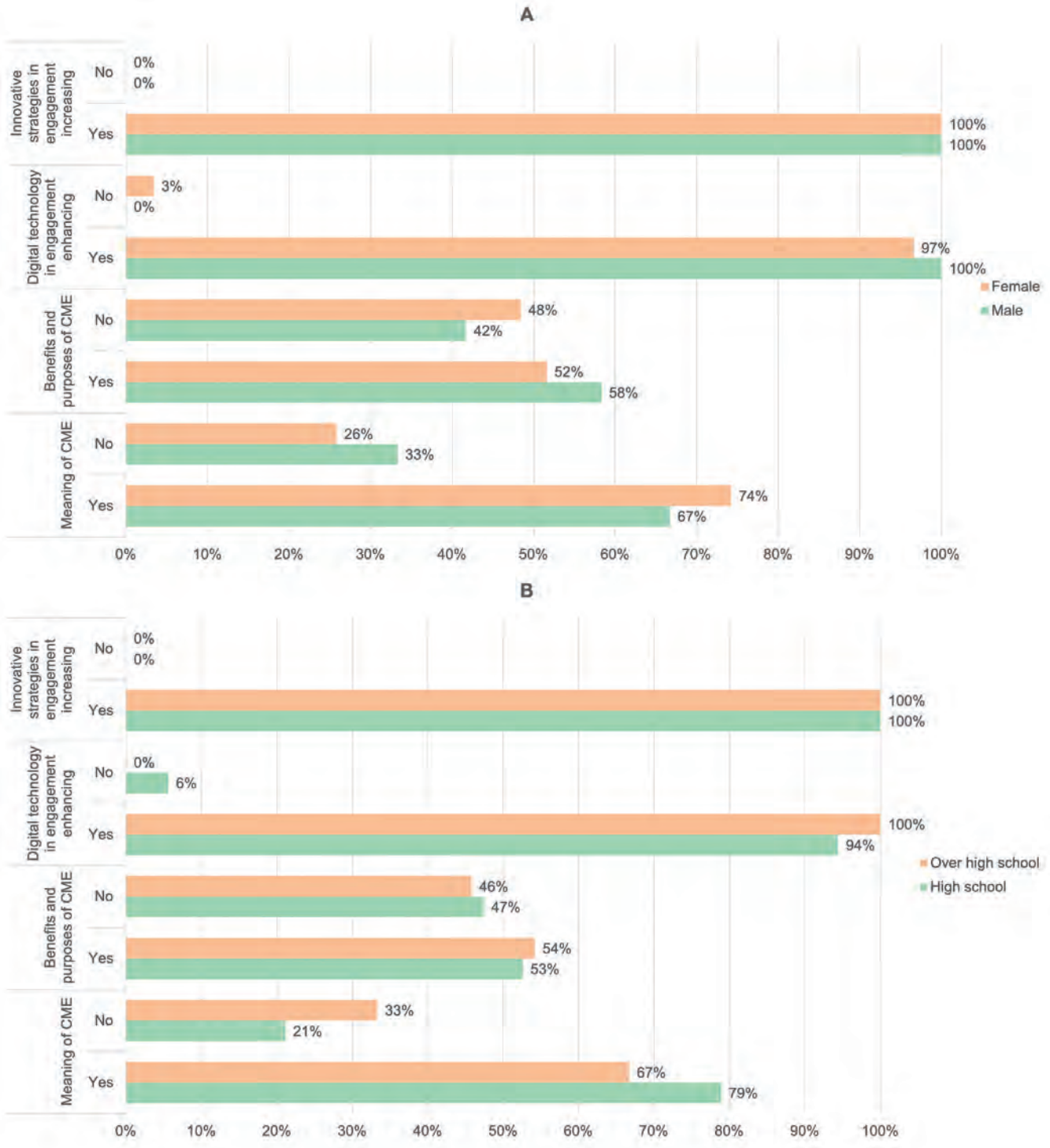
This study highlights how CME is perceived in a sample of Italian students as markedly impactful in enhancing healthcare professionals' knowledge and fundamental for professional development. Also previous studies carried out in Italy underlined such vital role (21,22), but lack of the investigation on the specific role of modern approaches. Specifically, our study highlights that engagement is perceived as equally important compared to traditional learning methods, emphasizing the need for interactive and motivating didactic approaches, given also that CME is mandatory and risks being perceived as a mere obligation without tangible benefits (22). Engagement in education refers to the active involvement, interest, and motivation of participants in their learning processes. Several factors enhance engagement in CME, such as the possibility of benefiting from relevant content, active learning methods, digital tools, and personalized learning. Digital tools like online platforms further boost users' engagement, while self-directed and competence-oriented learning allows healthcare providers to focus on areas most relevant to their practice, fostering greater involvement (23,24). As a consequence, high engagement leads to better knowledge retention, practical application of skills, and long-term learning outcomes (25,26). For these reasons, engagement offers an opportunity to make CME courses more appealing and effective, transforming them into meaningful learning experiences that enhance knowledge retention and ultimately improve the quality of care (27).

Active learning techniques such as simulation, role-playing, case-based learning, problem-based learning, gamification, team-based learning, and flipped classroom methods can increase motivation and foster active participation and are increasingly recognized for their potential to enhance engagement in CME (14). In this study, participants were familiar with simulation, role-playing, case-based learning, and problem-based learning, while gamification was less known. Chi-square analysis revealed that demographic factors, including gender, educational attainment, and occupational status, did not significantly influence perceptions of CME or engagement strategies.

Simulation emerged as the most familiar approach in the sample and is widely supported by literature as a highly effective method in CME of a wide range of disciplines (16, 28-32). It allows healthcare professionals to refine technical and non-technical skills in controlled settings, enhancing readiness for real-world challenges (18,33). However, low-fidelity simulations may interfere with training effectiveness, underscoring the need for realistic scenarios (34).

Role-playing is an active learning technique that allows healthcare professionals to adopt various roles within clinical scenarios, fostering skills such as empathy, communication, and teamwork. Research highlights its effectiveness in enhancing empathy and strengthening interpersonal communication, which is critical in delivering high-quality care (35). In CME, role-playing is particularly relevant for improving non-technical skills, including patient interaction, conflict resolution, and interprofessional collaboration (36). There are studies that found that role-playing activities improve students' abilities (37). However, role-playing has limited evidence supporting its broader impact on CME, warranting further investigation (38).

Case-based learning is vastly used in medical education and training and familiar to the study population (39). Case analysis engages learners in critical thinking by presenting real-life or hypothetical patient cases for analysis and by making content directly relevant to clinical practice. This approach


A
Innovative strategies in engagement increasing
No
Yes
Digital technology in engagement enhancing
No
Yes
Benefits and purposes of CME
No
Yes
Meaning of CME
No
Yes
0%
0%
100%
100%
3%
0%
97%
100%
48%
42%
52%
58%
26%
33%
74%
67%
Female
Male
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
B
Innovative strategies in engagement increasing
No
Yes
Digital technology in engagement enhancing
No
Yes
Benefits and purposes of CME
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Meaning of CME
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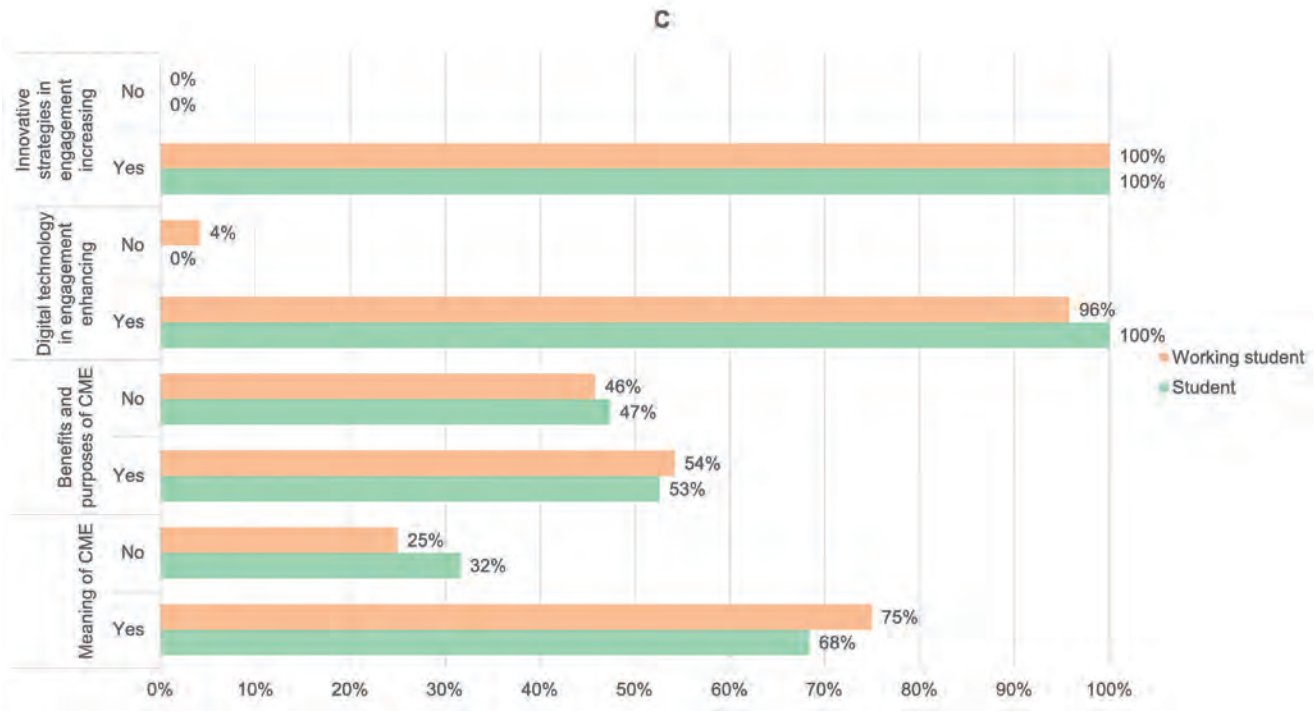

Figure 4. Chi-square tests conducted between dichotomous questions (perceived meaning of CME, benefits and purposes of CME, usefulness of digital technology to enhance educational engagement, perceived usefulness of innovative strategies to increase engagement, usefulness of personalized learning in the healthcare sector) and categorical variables: A) gender, B) educational attainment, C) occupational status.

is particularly effective in fostering diagnostic reasoning and decision-making skills (40). Evidence suggests that case-based learning in CME significantly improves diagnostic accuracy and encourages collaborative problem-solving among peers (41).

PBL is another method that has demonstrated considerable success in medical education (42). It enables healthcare professionals to develop critical thinking and problem-solving abilities by addressing real-world clinical issues (43). Studies indicate that PBL enhances engagement by fostering a self-directed learning approach (44), which is essential in CME where participants often have varying knowledge bases.

Gamification, though less familiar, holds significant potential to make CME more engaging, particularly in digital formats (45). While initial research supports its benefits in motivation and learning, further studies are required to validate its broader applicability, especially in healthcare sector (46-48).

Finally, team-based learning involves small-group activities where learners apply theoretical knowledge to complex cases whereas flipped classroom model involves an independent review of the lecture content before applying knowledge in interactive class sessions. Team-based learning fosters higher engagement levels and supports collaborative learning in medical education contexts (49) as well as flipped classroom. However, their specific impact on CME engagement remains underexplored, highlighting a critical gap for future research.

This study provides valuable insights into the familiarity and perceived utility of active learning techniques in CME in a sample of graduate and post-graduate students. This is especially relevant since all the participants were students in Public Health courses and expected to be exposed to CME within few years as learners and possibly also in the implementation of CME interventions. Therefore, one notable study strength lies in its focus on active learning approaches, addressing a critical gap in medical education research. The findings contribute to the growing body of evidence on engagement-enhancing strategies and emphasize the importance of linking theoretical knowledge with practical applications.

However, several limitations should be acknowledged. The small sample size and moderate response rate limits the generalizability of the findings to broader, more diverse populations. Despite attending (graduate) or having attended (post-graduate) Public Health courses in their educational path, and with all of them being exposed to CME, participant heterogeneity in terms of years and type of education further limits the generalization of the study findings. In addition, the questionnaire has been designed using expertise of co-authors, but it was not previously validated in this or other studies. However, since none of previous studies specifically investigated modern learning approaches in CME (21,22), the present one may represent a helpful pilot survey for planning future studies on the topic. The reliance on self-reported data without external validation introduces the possibility of response bias, as participants may have over- or under-estimated their familiarity and perceptions of engagement strategies. These limitations highlight the need for cautious interpretation of the results and suggest directions for future research to build on these findings. Furthermore, future research offers a valuable opportunity to explore the integration of active learning methods and competency-based education in CME. This focus aligns with the growing emphasis on competency-based work, as highlighted by a recent WHO publication, which underscores the need for healthcare professionals to meet defined skill and knowledge standards to address evolving healthcare challenges effectively (50). Investigating how active learning strategies can support competency development will be critical to ensuring that CME programs not only engage participants but also prepare them to deliver high-quality, patient-centered care in diverse and dynamic settings.

Conclusions

Active learning approaches are critical in enhancing engagement and improving CME outcomes. Techniques like simulation, role-playing, case-based learning, and problem-based learning are well-established for fostering practical and cognitive skills among healthcare professionals. Methods such as gamification, team-based learning, and flipped classroom are less known and used in medical education, thus requiring further implementation in educational programs to show their effectiveness in CME contexts.

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Riassunto

Conoscenze e percezione dei moderni approcci di apprendimento nell'Educazione Continua in Medicina: uno studio trasversale

Introduzione. L'Educazione Continua in Medicina (ECM) è essenziale per migliorare la performance professionale. I moderni metodi per l'ECM dovrebbero prioritizzare l'adattabilità e il coinvolgimento attraverso l'apprendimento interattivo ed esperienziale, permettendo di mantenere le conoscenze nel tempo, promuovendo l'applicazione delle competenze acquisite per affrontare le sfide sanitarie odierne. L'obiettivo di questo studio è valutare la conoscenza e l'importanza attribuita al coinvolgimento e alle moderne tecniche di apprendimento attivo nell'ECM da parte della popolazione italiana.

Metodi. Mediante uno studio pilota di tipo trasversale sono stati coinvolti studenti dell'Università di Modena e Reggio Emilia nel 2023. I dati sono stati raccolti attraverso un questionario composto da 17 domande per esploravano conoscenze e percezioni sull'ECM e sul coinvolgimento nell'educazione.

Risultati. Sono stati inclusi 43 partecipanti (età mediana di 25 anni, 72,1% donne). Il ruolo dell'ECM è riconosciuto dal 72,1% dei partecipanti, mentre il 53,5% conosceva i suoi benefici. Le risposte su scala *Likert* hanno mostrato un'alta percezione dell'importanza della ECM e del coinvolgimento (punteggi medi tra 3,79 e 4,40). Metodi attivi come la simulazione (68,3%) e il *role-playing* (65,9%) erano familiari al campione, mentre la ludicizzazione (36,6%) era molto meno conosciuta.

Conclusioni. Sebbene metodi come simulazione, *role-playing*, apprendimento basato sull'analisi di casi e il *problem-based learning* siano noti nella popolazione in studio per la loro forte evidenza di efficacia, approcci emergenti come la ludicizzazione e il *team-based learning* sono meno noti e richiedono maggiore diffusione nei programmi di educazione per mostrare i loro benefici.

References

1. Blomberg D, Stephenson C, Atkinson T, Blanshan A, Cabrera D, Ratelle JT, et al. Continuing Medical Education in the post COVID-19 pandemic era. JMIR Med Educ. 2023 Nov 15;**9**:e49825. doi: 10.2196/49825. PMID: 37966881; PMCID: PMC10687685.
2. Jang A, Kim MR, Lee SMK, Ha IH, Shin JY, McClain R, et al. Evaluating the effectiveness of online Continuing medical education during the COVID-19 pandemic. Med Teach. 2023 Aug;**45**(8):852-858. doi: 10.1080/0142159X.2023.2183787. PMID: 37013818.
3. Lugli C, Ferrari E, Filippini T, Grignolio Corsini A, Odone A, Vinceti M, et al. It's (not) rocket science: public health communication experience as expressed by participants to an international workshop. Popul Med. 2024 2024;**6**(July):1-7. doi: 10.18332/popmed/191254.
4. Palandri L, Urbano T, Pezzuoli C, Miselli F, Caraffi R, Filippini T, et al. The key role of public health in renova-

ting Italian biomedical doctoral programs. Ann Ig. 2024 May-Jun;**36**(3):353-362. doi: 10.7416/ai.2024.2592. PMID: 38236000.
5. Mazzoli R, La Torre M, Privitera VE, Sandig N, Filippini T, Vinceti M. Funding sources for public health research in Italy. Ann Ig. 2024 Nov 7. doi: 10.7416/ai.2024.2666. Epub 2024 Nov 7. PMID: 39526551.
6. McAdams CD, McNally MM. Continuing medical education and lifelong learning. Surg Clin North Am. 2021 Aug;**101**(4):703-715. doi: 10.1016/j.suc.2021.05.015. PMID: 34242611.
7. Amicosante AMV, Eugeni E, Bernardini F, Cavallo AV, Paone S, Guglielmi E, et al. [Continuing medical education (Cme/Ecm) on medical devices in Italy: a review for the 2019-2021 period.]. Recenti Prog Med. 2024 Feb;**115**(2):76-81. doi: 10.1701/4197.41840. PMID: 38291932.
8. Filippini T, Paduano S, Veneri F, Barbolini G, Fiore G, Vinceti M. Adverse human health effects of climate change: an update. Ann Ig. 2024 May-Jun;**36**(3):281-291. doi: 10.7416/ai.2024.2595. PMID: 38303639.
9. Accreditation Council for Continuing Medical Education. Definition of CME; 2007. Available from: https://accme.org/rule/cme-content-definition-and-examples/ [Last accessed: 2024 December 18].
10. Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, et al. Effectiveness of continuing medical education. Evid Rep Technol Assess (Full Rep). 2007 Jan;(149):1-69. doi. PMID: 17764217; PMCID: PMC4781050.
11. Schrock JW, Cydulka RK. Lifelong learning. Emerg Med Clin North Am. 2006 Aug;**24**(3):785-795. doi: 10.1016/j.emc.2006.05.012. PMID: 16877143.
12. Garattini L, Gritti S, De Compadri P, Casadei G. Continuing Medical Education in six European countries: a comparative analysis. Health Policy. 2010 Mar;**94**(3):246-254. doi: 10.1016/j.healthpol.2009.09.017. PMID: 19913324.
13. Cullen MW, Geske JB, Anavekar NS, McAdams JA, Beliveau ME, Ommen SR, et al. Reinvigorating continuing medical education: meeting the challenges of the digital age. Mayo Clin Proc. 2019 Dec;**94**(12):2501-2509. doi: 10.1016/j.mayocp.2019.07.004. PMID: 31806103.
14. Bucklin BA, Asdigian NL, Hawkins JL, Klein U. Making it stick: use of active learning strategies in continuing medical education. BMC Med Educ. 2021 Jan 11;**21**(1):44. doi: 10.1186/s12909-020-02447-0. PMID: 33430843; PMCID: PMC7798232.
15. Wells JC. Leading organizational learning. HCA Healthc J Med. 2021;**2**(1):29-33. doi: 10.36518/2689-0216.1245. PMID: 37424888; PMCID: PMC10324730.
16. Abulebda K, Auerbach M, Limaiem F. Debriefing techniques utilized in medical simulation. 2022 Sep 26. In: StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2025 Jan-. PMID: 31536266.
17. Forsetlund L, O'Brien MA, Forsen L, Reinar LM, Okwen MP, Horsley T, et al. Continuing education meetings and workshops: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2021 Sep 15;**9**(9):CD003030. doi: 10.1002/14651858.CD003030.pub3. PMID: 34523128; PMCID: PMC8441047.
18. Herrera-Aliaga E, Estrada LD. Trends and innovations of simulation for twenty first century medical education. Front Public Health. 2022;**10**:619769. doi: 10.3389/fpubh.2022.619769. PMID: 35309206; PMCID: PMC8929194.
19. Verzelloni P, Adani G, Longo A, Di Tella S, Santunion AL, Vinceti M, et al. Emergency department crowding: An assessment of the potential impact of the See-and-Treat protocol for patient flow management at an Italian hospital. Int Emerg Nurs. 2025 Feb;**78**:101569. doi: 10.1016/j.ienj.2024.101569. Epub 2025 Jan 9. PMID: 39793341.
20. Vinceti SR, Filippini T. Revising the legislation of Ethics Committees to ease biomedical research in humans across the world: lessons from the COVID-19 emergency. Acta Biomed. 2022 May 11;**93**(2):e2021579. doi: 10.23750/abm.v93i2.12582. PMID: 35546005; PMCID: PMC9171886.
21. Ciaschi A, Caprara A. [Continuing education pathways. The training experience of the agency for public health Laziosanita]. Ann Ig. 2009 Jul-Aug;**21**(4):357-363. doi. PMID: 19798912.
22. Coniglio AM, Calvo C, Marranzano M. [Usefulness and quality of Continuing Medical Education programs: doctors' points of view]. Ig Sanita Pubbl. 2014 May-Jun;**70**(3):305-312. PMID: 25194121.
23. Barbina D, Riccardo F, Di Pucchio A, Del Manso M, Mammoli M, Croci R, et al. Public Health Workforce training Laboratorium: Pilot e-Learning course on CBE and PBL models. Eur J Public Health. 2022;**32**(Supplement_3):ckac131.091. doi: 10.1093/eurpub/ckac131.091.
24. Mazaccara A, Privitera G, Di Pucchio A, Barbina D, Bertinato L, Mistretta A, et al. Need for a competency-based approach for the Public Health Workforce training: the ISS proposal. Eur J Public Health. 2022;**32**(Supplement_3):ckac131.028. doi: 10.1093/eurpub/ckac131.028.
25. Milani C, Naldini G, Occhini G, Pontalti I, Baggiani L, Nerattini M, et al. Enhancing Primary Health Care through Interprofessional education: Insights from a Training Workshop. Ann Ig. 2024 Sep-Oct;**36**(5):513-524. doi: 10.7416/ai.2024.2631. Epub 2024 Apr 18. PMID: 38648012.
26. Bond M, Buntins K, Bedenlier S, Zawacki-Richter O, Kerres M. Mapping research in student engagement and educational technology in higher education: a systematic evidence map. Int J Educ Technol High Educ. 2020 Jan 22;**17**(1):2. doi: 10.1186/s41239-019-0176-8.
27. Blandi L, Odone A. The synergies of University Education and Primary Health Care to meet populations health needs. Ann Ig. 2023 Jan-Feb;**35**(1):121-124. doi: 10.7416/ai.2022.2545. PMID: 36222606.
28. Kennedy CC, Cannon EK, Warner DO, Cook DA. Advanced airway management simulation training in medical education: a systematic review and meta-analysis. Crit Care Med. 2014 Jan;**42**(1):169-178. doi: 10.1097/CCM.0b013e31829a721f. PMID: 24220691.
29. Brunette V, Thibodeau-Jarry N. Simulation as a tool to ensure competency and quality of care in the Cardiac Critical

Care unit. Can J Cardiol. 2017 Jan;**33**(1):119-127. doi: 10.1016/j.cjca.2016.10.015. PMID: 28024550.
30. Abbas JR, Chu MMH, Jeyarajah C, Isba R, Payton A, McGrath B, et al. Virtual reality in simulation-based emergency skills training: a systematic review with a narrative synthesis. Resusc Plus. 2023 Dec;**16**:100484. doi: 10.1016/j.resplu.2023.100484. PMID: 37920857; PMCID: PMC10618508.
31. Garnier A, Vanherp R, Bonnabry P, Bouchoud L. Use of simulation for education in hospital pharmaceutical technologies: a systematic review. Eur J Hosp Pharm. 2023 Mar;**30**(2):70-76. doi: 10.1136/ejhpharm-2021-003034. PMID: 34949651; PMCID: PMC9986932.
32. Yahya LB, Naciri A, Radid M, Chemsi G. Immersive simulation in nursing and midwifery education: a systematic review. J Educ Eval Health Prof. 2024;**21**:19. doi: 10.3352/jeehp.2024.21.19. PMID: 39111774.
33. Willis RE, Van Sickle KR. Current status of simulation-based training in graduate medical education. Surg Clin North Am. 2015 Aug;**95**(4):767-779. doi: 10.1016/j.suc.2015.04.009. PMID: 26210969.
34. Curtis MT, DiazGranados D, Feldman M. Judicious use of simulation technology in continuing medical education. J Contin Educ Health Prof. 2012 Fall;**32**(4):255-260. doi: 10.1002/chp.21153. PMID: 23280528; PMCID: PMC3691844.
35. Kaplan-Liss E, Lantz-Gefroh V, Bass E, Killebrew D, Ponzio NM, Savi C, et al. Teaching medical students to communicate with empathy and clarity using improvisation. Acad Med. 2018 Mar;**93**(3):440-443. doi: 10.1097/ACM.0000000000002031. PMID: 29059072.
36. Carney PA, Dietrich AJ, Freeman DH, Jr., Mott LA. A standardized-patient assessment of a continuing medical education program to improve physicians' cancer-control clinical skills. Acad Med. 1995 Jan;**70**(1):52-58. doi: 10.1097/00001888-199501000-00014. PMID: 7826445.
37. Kesten KS. Role-play using SBAR technique to improve observed communication skills in senior nursing students. J Nurs Educ. 2011 Feb;**50**(2):79-87. doi: 10.3928/01484834-20101230-02. PMID: 21210611.
38. Pearse W, Saxon R, Plowman G, Hyde M, Oprescu F. Continuing education outcomes for advance care planning: a systematic review of the literature. J Contin Educ Health Prof. 2021 Jan 1;**41**(1):39-58. doi: 10.1097/CEH.0000000000000323. PMID: 33433128.
39. McLean SF. Case-based learning and its application in medical and health-care fields: a review of worldwide literature. J Med Educ Curric Dev. 2016 Jan-Dec;**3**:39-49. doi: 10.4137/JMECD.S20377. PMID: 29349306; PMCID: PMC5736264.
40. Kassirer JP. Teaching clinical reasoning: case-based and coached. Acad Med. 2010 Jul;**85**(7):1118-1124. doi: 10.1097/acm.0b013e3181d5dd0d. PMID: 20603909.
41. Thistlethwaite JE, Davies D, Ekeocha S, Kidd JM, MacDougall C, Matthews P, et al. The effectiveness of case-based learning in health professional education. A BEME systematic review: BEME Guide No. 23. Med Teach. 2012;**34**(6):e421-444. doi: 10.3109/0142159X.2012.680939. PMID: 22578051.
42. Al-Azri H, Ratnapalan S. Problem-based learning in continuing medical education: review of randomized controlled trials. Can Fam Physician. 2014 Feb;**60**(2):157-165. doi. PMID: 24522680; PMCID: PMC3922562.
43. Gongora-Ortega J, Segovia-Bernal Y, Valdivia-Martinez Jde J, Galaviz-DeAnda JM, Prado-Aguilar CA. Educational interventions to improve the effectiveness in clinical competence of general practitioners: problem-based versus critical reading-based learning. BMC Med Educ. 2012 Jul 11;**12**:53. doi: 10.1186/1472-6920-12-53. PMID: 22784406; PMCID: PMC3814588.
44. Al-Eyd G, Seki T, Griffin DP. A 10-step process to align problem-based learning with accreditation expectations for self-directed and lifelong learning. J Med Educ Curric Dev. 2024 Jan-Dec;**11**:23821205241255190. doi: 10.1177/23821205241255190. PMID: 38784848; PMCID: PMC11113030.
45. Gentry SV, Gauthier A, L'Estrade Ehrstrom B, Wortley D, Lilienthal A, Tudor Car L, et al. Serious gaming and gamification education in health professions: systematic review. J Med Internet Res. 2019 Mar 28;**21**(3):e12994. doi: 10.2196/12994. PMID: 30920375; PMCID: PMC6458534.
46. Telner D, Bujas-Bobanovic M, Chan D, Chester B, Marlow B, Meuser J, et al. Game-based versus traditional case-based learning: comparing effectiveness in stroke continuing medical education. Can Fam Physician. 2010 Sep;**56**(9):e345-351. doi. PMID: 20841574; PMCID: PMC2939136.
47. Westenhaver ZK, Africa RE, Zimmerer RE, McKinnon BJ. Gamification in otolaryngology: a narrative review. Laryngoscope Investig Otolaryngol. 2022 Feb;**7**(1):291-298. doi: 10.1002/lio2.707. PMID: 35155810; PMCID: PMC8823161.
48. Donoso F, Peirano D, Longo C, Apalla Z, Lallas A, Jaimes N, et al. Gamified learning in dermatology and dermoscopy education: a paradigm shift. Clin Exp Dermatol. 2023 Aug 25;**48**(9):962-967. doi: 10.1093/ced/llad177. PMID: 37155594.
49. Will KK, Essary A. Competency-based interprofessional continuing education focusing on systems thinking and health care delivery for health care professionals. J Contin Educ Health Prof. 2021 Apr 1;**41**(2):153-156. doi: 10.1097/CEH.0000000000000330. PMID: 33394820.
50. World Health Organizaton (WHO). Global competency and outcomes framework for the essental public health functons; 2024. Available from: hvps://www.who.int/publicatons/i/item/9789240091214. [Last accessed: 2024 December 18].

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Supplementary material – Study questionnaire

Survey on the Importance of Continuous Education in the Healthcare Sector

1. Which gender do you identify with?
   – Female
   – Male
   – Non-binary
   – Not listed, please specify: …

2. What is your year of birth?
   (dropdown menu)

3. What is your employment status?
   – Student
   – Student and worker

4. If you selected “Student and worker” in the previous question, please specify your occupation:
   (free text)

5. What is the highest level of education you have attained?
   – High school diploma
   – Non-university tertiary diploma
   – Bachelor’s degree
   – Master’s degree
   – First-level university master’s
   – Second-level university master’s
   – PhD/postgraduate specialization
   – Not listed, please specify: …

6. Are you familiar with the definition of Continuing Medical Education?
   – Yes
   – No

7. To what extent do you believe that Continuing Medical Education impacts the knowledge of healthcare sector operators?
   (Likert scale; 1=low, 5=high)

8. Do you consider participation in Continuous Medical Education for healthcare personnel important?
   (Likert scale; 1=low, 5=high)

9. Are you aware of the objectives and benefits of Continuing Medical Education?
   – Yes
   – No

10. Which active approaches to increasing engagement have you heard of?
    (multiple choice)
    – Interest increase
    – Memorisation improvement
    – Exclusively technology-based
    – Practical skills development
    – Effective only for senior students
    – Passiveness decrease

11. How important do you think engagement is for health sector workers?
    (Likert scale; 1=low, 5=high)

12. Do you think that the correct use of social media and collaborative platforms can promote engagement?
(Likert scale; 1=low, 5=high)

13. Do you think digital technologies are useful for improving engagement in education?
– Yes
– No

14. Do you think innovative strategies are useful for actively engaging personnel in the healthcare sector?
– Yes
– No

15. Which active approaches are you familiar with?
(multiple choice)
– Simulation
– Gamification
– Role playing
– Case-Based analysis
– Team-Based learning
– Problem-Based learning
– Flipped classroom

16. Do you consider personalized learning useful in the healthcare sector?
– Yes
– No

17. If you answered “No” to the previous question, please briefly explain why:
(free text)

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A critical analysis of national dementia plans: comparison of preventive strategies in five European countries

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Keywords: Dementia; health policy; framework; prevention; risk reduction
Parole chiave: Demenza; politiche sanitarie; framework; prevenzione

Abstract

Background. *Preventive measures can avert up to 45% of dementia cases worldwide. The aim of the study is to analyse some selected national dementia prevention strategic plans.*
Methods. *A qualitative comparative analysis was performed between national dementia plans of the European countries with the best healthy life expectancy among the elderly. The national dementia plans of France, Ireland, Italy, Spain and Sweden were included. The consensus on priority actions and key elements of prevention policies was evaluated, according to the World Health Organization recommendations and to an analysis tool designed for evaluating chronic diseases policies.*
Results. *All the countries emphasized the importance of prevention policies within their dementia plans and established monitoring committees. However, not all countries defined timelines for policy implementation and only Spain updated its national plan so far. The integration of dementia prevention with other chronic disease preventive campaigns is still lacking, and also a clear allocation of funds for dementia plans is absent so far.*
Conclusions. *All countries extensively followed the World Health Organization's recommendations. However, the plans have not been updated. Thus, they do not address all the current known risk factors for dementia, preventing only a fraction of potentially preventable cases. Moreover, the need for financial support in national dementia plans are critical but inadequately addressed, with inconsistent or undefined funding sources to implement their goals.*

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Background

Dementia is one of the most prevalent neurological disorders, the fourth leading cause of Disability-adjusted life years (DALYs) and the seventh leading cause of death worldwide (1-3). Currently, the global estimates of dementia prevalence in individuals aged ≥65 years are at 6.9%, and in the European Region is even higher at 8.5% (4). Dementia prevalence is still increasing and will more than double by 2050 (5,6). For Europe's 14.1 million people with dementia, medical, social, and private care cost US$ 31,144 per person (4). Health agencies and governments, especially in Europe, recognised dementia as a key area of political priority. Indeed, they are planning, implementing and monitoring targeted dementia policies and programmes to counteract its major impact on families, communities and economies (7,8). Until now, dementias have no effective and decisive therapy, and the clinical benefit and meaning of the new treatments on the market is not established yet (9). In this scenario, prevention plays the most important role. It is important for the future economic health of our societies to invest money into preventing dementia and its short-term and long-term effects (10,11). In 2020, the Lancet Commission identified 12 risk factors underlying the onset of dementia (12) acting throughout a person's life span, including "lower level of education, hearing loss, traumatic brain injury, hypertension, alcohol abuse, obesity, smoking, depression, social isolation, physical inactivity, diabetes and air pollution" (13). In 2024, the Lancet Commission identified 2 additional risk factors: visual loss and high LDL cholesterol (14). If we could eliminate these 14 risk factors, addressing them over the entire life span of our population, it is estimated that our societies could prevent up to 45% of current cases of dementia in Europe and worldwide (13-16). Primary prevention should act both on individuals at high-risk and also on those at low and moderate risk as well – through a population approach – as it has a major impact on the occurrence of the diseases and on the health of the population (17). There are World Health Organization's (WHO) recommendations and scientific evidence aimed at reducing risk both at the individual level and at the population level (18-20). Western Europe is expected to have the smallest increase in prevalence of dementia cases in 2050 (+74%), in comparison with all countries globally (+166%), as it has already begun working to limit risk factors (6). In this regard, a comparative analysis of European health policies is the key to identify and understand what actions countries are pursuing and to identify possible virtuous strategies (21). Thus, the aim of this paper is to provide an analysis of selected national strategies related to prevention policies for dementia.

Methods

Our study selected a panel of five European countries with a better healthy life expectation among the elderly, according to specific inclusion criteria (see paragraph 2.1). National dementia plans were searched through individual governmental health ministries and departments websites by an author (LB) as available by 1st January 2025. The documents were downloaded in the original language, translated into English by a professional software (DeepL PRO) and verified by another Author (TC). Data extraction and analysis of selected countries' national dementia plans were conducted by LB and TC. Documents interpretations were discussed in multiple online meetings, comparing them with reference documents (see paragraph 2.2) in agreement with qualitative methods (see paragraph 2.3). Table 1 presents the conclusive list of countries and national dementia strategies that were included in the analysis.

1. Inclusion criteria

The top-5 ranked countries were selected for the analysis according to the most updated WHO indicator "Healthy Life Expectancy at Age 60" (HALE), which provides both non-fatal and fatal health outcomes in a summary measure of average levels of population health (22). This indicator was considered appropriate for comparing the impact of long-term disabling conditions, as dementia, on the health of different countries' populations. In addition, to make the analysis consistent and the plans comparable, we included countries satisfying the following criteria: 1) be a member state of the European Union for at least 20 years (since 2002); 2) have a population of at least 5 million inhabitants. Indeed, countries with larger populations might have more diverse cultural, ethnic, and social groups, each with its own health beliefs, practices, and needs, and these can play a significant role in how health policies are framed and how effective they are.

2. Reference documents

The analysis of national dementia plans was guided by two reference documents: the first one recommends specific policies or actions for dementia prevention at national level, and the second one to assess the plans as well-designed policy tools.

Table 1 - Selected countries and their National Dementia Plans

Country	Document	Issuing Body	Link
France	Plan Maladies Neuro-Dégénératives	Ministère des Affaires sociales, de la Santé et des Droits des femmes, Conception et réalisation	https://sante.gouv.fr/soins-et-maladies/maladies/maladies-neurodegeneratives/article/feuille-de-route-maladies-neuro-degeneratives-2021-2022
Ireland	The Irish National Dementia Strategy	Department of Health	https://www.hse.ie/eng/dementia-pathways/about/the-national-dementia-strategy/
Italy	Piano Nazionale Demenze	Presidenza del Consiglio dei Ministri Conferenza Unificata	https://www.iss.it/le-demenze-piano-nazionale-demenze
Spain	Plan Integral de Alzheimer y otras Demencias	Ministerio De Sanidad, Consumo Y Bienestar Social	https://www.sanidad.gob.es/profesionales/saludPublica/docs/Plan_Integral_Alhzeimer_Octubre_2019.pdf
Sweden	Nationell strategi för omsorg om personer med demenssjukdom	Socialdepartementet	https://www.regeringen.se/ or https://www.alzheimer-europe.org/sites/default/files/2021-10/Sweden%20National%20Dementia%20Strategy.pdf

2.1 Reference document 1: Policies or actions for dementia prevention

The seven themes used for the analysis and the actions within them were selected from a reference document, the *Global action plan on the public health response to dementia 2017–2025* (20), published by WHO in 2017. This document was identified through an extensive ad-hoc scoping review (see Supplementary material 1). The seven action areas from the *WHO Global action plan* served as reference, because they propose actions to member states for supporting or fostering dementia prevention and care.

2.2 Reference document 2: health policy assessment tool

The additional key elements were chosen from a policy evaluation tool by Cheung et al, *Health policy analysis: a tool to evaluate in policy documents the alignment between policy statements and intended outcomes* (23), which aims to evaluate the alignment between policy statements and intended outcomes of chronic illness policy document. The tool encompasses a structured framework designed to assess the inclusion of essential components within the policy text.

3. Qualitative analysis

A qualitative comparative analysis was performed since it allows for a rigorous and systematic investigation of complex situations through a small case number (21). The two reference documents derived from scientific evidence and recommendations to member states of international agencies provide strength to the analysis. The adherence of national dementia plans to the preventive recommendations included in the reference documents, as well as the discussion of their similarities and differences, permits to build operational recommendations for future preventive strategies (24).

According to the *Global action plan on the public health response to dementia 2017–2025*, we evaluated the adherence of national dementia plans to the recommended preventive priority actions, organized into seven themes (see Table 2). To consider a priority action as present, it had to be explicitly mentioned in the national dementia plans, thus preventing the possibility of interpretation bias.

We investigated the presence of further additional key elements, according to the reference document *Health policy analysis: a tool to evaluate in policy documents the alignment between policy statements and intended outcomes*, for the dementia plans' implementation and evaluation (see Table 3).

A consensus was reached when either all countries adhered to the specified criteria or when a single country expressed a divergence. For example, all countries shared the importance of providing training to health and social staff for prevention of stress of carers, except for Italy, hence this was still classified as a consensual criterion. The criteria on which agreement was not reached represent areas for improvement, as they come from recommendations issued by the reference documents above.

Table 2 - Analysis of priority actions of National Dementia Plans among selected countries

Priority areas	Actions	France	Ireland	Italy	Spain	Sweden
Dementia as a Public Health priority	Develop a national Dementia plan	+	+	+	+	+
	Update the national Dementia	-	-	-	+	-
	Set up a Dementia unit	+	+	+	+	+
Dementia awareness and friendliness	Promote awareness campaign	+	+	+	+	+
	Promote early diagnosis	+	+	+	+	+
Dementia risk reduction	Integrate with other prevention programmes	+	+	-	+	-
	Address obesity	-	+	-	+	-
	Address tobacco use	-	+	-	+	-
	Address alcohol misuse	-	+	-	+	-
	Promote cognitive stimulation	+	+	-	+	-
	Promote social engagement	+	+	+	+	+
Dementia diagnosis, treatment, care and support	Promote case-finding	-	-	-	-	-
	Build knowledge and skills of health workers on prevention	+	+	+	+	+
	Shift from hospitals towards community-based care setting interventions	+	+	-	+	-
Support for Dementia carers	Provide information and training to carers about caregiving	+	+	+	+	+
	Provide training to health and social staff for prevention of stress of carers	+	+	-	+	+
	Develop interventions for protection of carers and/or stigma avoidance	+	+	+	+	-
Information systems for dementia	Develop specific national surveillance and monitoring systems	+	+	+	+	+
	Map resources for prevention and risk reduction	+	+	+	+	+
	Collect epidemiological data	+	+	+	+	+
Dementia research and innovation	Develop national research agenda on prevention	+	+	-	+	+
Last update	Year of publication	2014	2014	2015	2019	2018
Timeframe	Years of implementation	2014-19	U	U	2019-23	2018-22

Key identifiers: [+] Present, [-] Not present, [U] Undetermined

Results

The data collected from national dementia plans of 5 selected countries were analysed under the lens of prevention. The documents are developed differently. Indeed, the French and Italian national dementia plan had an action-oriented structure, organised into several objectives to reach. The Irish, Spanish and Swedish national dementia plans had a more traditional structure divided in chapters, including the background, objectives, monitoring and other specific issues. Given the methodology of the current study, data were reconstructed under the seven priority areas according to the WHO reference document (see Table 2).

According to the reference document for health policy assessment, further key elements which structure a plan intended for making an effective change to the system were evaluated (see Table 3).

Discussion

In this study, we analysed dementia prevention policies in official national dementia plans of five European countries.

Table 3 - Analysis of key elements of National Dementia Plans among selected countries

Key elements	Description	France	Ireland	Italy	Spain	Sweden
Accessibility	The policy document is accessible online	+	+	+	+	+
Goals	The goals are explicitly stated	+	+	+	+	-
	The action centers on improving the health of the population	+	+	+	+	+
Financial support	The cost of condition to community has been mentioned	-	+	+	+	-
	Estimated financial resources for implementation of the policy is given	-	-	-	-	-
	Allocated financial resources for implementation of the policy are clear	-	-	-	-	+
Monitoring & evaluation	The policy indicated monitoring and evaluation mechanisms	+	+	+	+	+
	The policy nominated a committee or independent body	+	-	+	+	+
	The data were collected before, during and after the introduction of the new policy	-	-	+	+	+
Public opportunities	Multiple stakeholders are involved	+	+	+	+	+

Key identifiers: [+] Present, [-] Not present

1. Areas of consensus and divergence among analysed plans

All countries recognized, since many years, the importance to develop a national dementia plan, especially France, which published the first plan in 2001. All countries identified an agency or committee to implement their plans and to monitor their progresses and achievements, but with heterogeneous composition and competencies in different legislative and organizational contexts. For example, France decided to include representatives of patients' associations, professional bodies, healthcare facilities, local and governmental authorities, and other stakeholders; Spain followed a similar strategy to France, identifying also the names of representatives. Italy established a list of institutions, including Ministry of Health, national Agencies and Bodies, Regions, and patients' associations. Sweden delegated the monitoring function to the National Board of Health and Welfare. Ireland decided to define it in a subsequent law.

Within the area of *dementia awareness and friendliness, dementia and risk reduction* area, and in the *dementia diagnosis, treatment, care and support* area, all countries recognised the necessity of allowing people with dementia to engage in the community and maximize their autonomy. All countries emphasised the relevance of promoting social engagement, intended as involvement of all the stakeholders in advocacy, policy, planning, legislation, service provision and monitoring. Furthermore, all countries planned to increase the knowledge and abilities of health personnel, with a special focus on promoting early diagnosis. In particular, Ireland promoted awareness-raising, information and training, specifying the importance to extend these activities to primary care professionals, caregivers and the general population (25). In all plans, also the importance of early diagnosis has been emphasised, as it has been recognised for more than 2 decades as a key point in the clinical pathway that can improve the quality of life of the patients and carers (26). On the other hand, the use of case-finding was never included. Indeed, its appropriateness in clinical practice is currently limited by gaps in the evidence base (27-30).

For actions in *Support for Dementia carers*, the prevention of stress and stigma towards patients and caregivers has been included in almost all national strategies except for Sweden. Caregivers of people living with dementia face significant challenges, including burnout and increased risk of depression (31). Multicomponent interventions, such as psychological input, psychoeducation, and training courses, have been found to be effective in reducing caregiver burden and stress and promote prevention (32,33). These findings underscore the need for comprehensive support programs that address the unique needs of caregivers. Indeed, training programmes for caregiving have also always been mentioned, recognising *Support for Dementia carers* as a priority area.

To establish Information systems for dementia, all

countries fostered the collection of epidemiological data, the mapping of resources and the implementation of a specific national surveillance system. Among them, the Swedish Dementia Registry (SveDem), developed in 2007, with the aim to improve the quality of diagnostic work-up, treatment and care of patients with dementia disorders in Sweden, represents an exceptional example (34). Every year, a report from this database is released to the public to let political and administrative leaders, as well as medical and care professionals, know about the present quality of services. (34).

Finally, countries found consensus under the priority area *Dementia research and innovation*. France devoted an entire section to the development and coordination of research on neurodegenerative diseases, including prevention as priority area, as well as Ireland. Spain devoted an entire section to research, within which it defines actors, priorities and objectives, counting prevention as one of the research areas to be investigated. These included the importance of increasing public and private funding and improving collaboration and coordination between the different centres and consortia carrying out research (35). Sweden included a section on research, which stated that there are significant gaps in knowledge in the field of dementia prevention. Italy only mentioned the importance of research to improve the prevention, diagnosis and treatment of the disease, without providing any further articulation.

Turning to the key elements of chronic disease policies, all countries have made their documents easily *accessible* online on their official governmental websites. The *objectives* have been clearly spelled out by France, Ireland, Italy, and Spain. Only Sweden articulated it differently from the other countries, not listing or tabulating explicit objectives, but rather defining strategic actions. France identified 96 action points which were qualitatively described, but only part of them could be quantitatively measured. In contrast, Ireland and Italy identified respectively 14 and 17 priority actions, and most of them can be measured quantitatively. Spain stated 20 priority actions and all of them were well described and could be easily measured quantitatively.

All countries implemented *monitoring and evaluation mechanisms*. However, not all the countries collected data before, during and after the introduction of the plan. Indeed, bridging the gap between data collection, research, and policymaking, is still a major challenge (36). Moreover, the importance *of stakeholders' involvement* was acknowledged as a public opportunity of collaboration for the implementation of the policy by all countries, as they included scientific societies and patients and caregivers' associations in the monitoring and evaluation processes. Finally, constructive health funding policy discussion is required to develop a common understanding between health sector leaders and central budget authorities to achieve health policies objectives (37); however, all this requires several modifications that are mentioned in the following section.

2. Key targets for improvement

The area of risk reduction is the one that requires most considerations. The WHO recommended to integrate dementia prevention with other chronic diseases campaigns (20). This necessitated cross-sectoral collaboration between diverse domains at the regional and local levels to develop preventative actions. Such calls have been recognised in the French, Irish, and Spanish dementia plans. However, given the years of updating the different plans, the risk factors on which to act with a population-based preventative approach are missing or incomplete. As the WHO recommendations were published before the last updated evidence (13,14), they focus only on preventive interventions against smoking, alcohol and obesity (20). These represent the risk factors that would only reduce 7 out of 45% of potentially preventable dementia cases, not including the remaining 38% (13,14). Planning, coordination and implementation of population-based preventive interventions on the 14 risk factors for dementia are currently the most effective action in the dementia challenge and should be an integrated public health priority in the health policies of all countries (13,14). This evidence emerged also in England, where a review of policies and strategies at local level underlined the importance of these preventive interventions delivered in primary care (25).

Furthermore, only the French, Irish, and Spanish plans provided any direction on the transition from hospital to primary care. Community-based care for dementia patients is essential but its sustainability may be limited by inconsistent funding and fragmented supply (38).

On this regard, a key element as *Financial support* was not included in the national dementia plans. The estimated and allocated resources for the plans' implementation were not clearly stated by the countries. The Irish, Italian and Spanish plans mentioned the cost of condition to community, and

only the Swedish partially reported the allocation of financial resources for the implementation of the plan, but they did not meet the recommendations of WHO.

For more than 10 years, dementias have been launched as a public health priority by the WHO (8). Despite that, not all countries included in this analysis defined timeframes for policy implementation and only the Spanish plan was up-to-date. France added a roadmap for the years 2021 and 2022 to its strategy 2014-19. However, developing and updating plans is an important target of WHO by 2025, which aims to reach 75% of member states to see dementias recognised as a public health priority globally (20). These, should take into account the distribution and impact of the disease among their populations, as incidence and mortality are changing (39).

3. Limitations and strengths of this paper

To the best of our knowledge, it is the first international comparative analysis between different plans related to people living with dementia and represents a first step toward understanding the international development of prevention policies for dementia. The selection of assessment areas was based on identified reference documents and provided clear frameworks to perform the qualitative analysis. The inclusion criteria selected countries in the same European legislative frame and with an historical attention to dementia as public health challenge, allowing a better and more logical comparison of plans.

This critical analysis is not aimed to provide insights into the actual plans' implementation because of the chosen methodology of document analysis. In addition, national dementia plans may be linked or referred to in other national policy documents that provide indications for chronic diseases, such as actions aimed at caregivers or dementia patients. Interacting with each plan's stakeholders and policymakers can help improve future policy analysis. Moreover, the texts were analysed as English-language translations by a professional software, which may have missed nuances. Despite the fact that our study focused on European countries with comparable health systems, the lack of countries such as Japan, the United States, South Korea, and Australia limits its worldwide generativity and may be addressed in future research.

Conclusions

This study analyses how some different European national plans tried to prevent dementia and whether countries adequately addressed it through WHO's recommendations and evidence-based interventions.

All countries extensively followed the WHO's recommendations in their national plans about many priority areas, such as developing awareness campaigns, promoting social participation, supporting caregivers, and fostering early diagnosis. However, given the global concern due to its growing prevalence, the plans did not address all the known risk factors to prevent dementia. These plans need for more comprehensive and timely approaches, as they vary in their completeness and year of update. Risk reduction for dementia requires more attention in the political agenda, calling for the alignment with WHO's recommendations in this priority area and new evidence from the *Lancet Commission for Dementia prevention, intervention, and care*. Only the Spanish plan is currently updated, still stressing the importance of raising awareness among politicians in putting dementia-related policies on the governmental agenda priorities.

National dementia plans recognised Monitoring Agencies or Committees as crucial for ensuring plan execution and success, but they require updated information. At the same time, the countries differed in their approaches to collecting and analysing epidemiological data to inform policymakers. There was still a lack of comprehensive collecting before, during, and after policy implementation. More investments and efforts must be focused on data collection for monitoring and developing data-driven policy. In this regard, only the Swedish Dementia Registry represents a successful example.

This study identifies also gaps in setting clear timeframes for policy implementation and providing adequate financial resources for the execution of these plans. There is also a call for greater planning, coordination, and implementation of population-based preventive interventions, also integrating them with other chronic diseases policies.

In conclusion, to address the identified areas of improvement, this study provides clear recommendations for policymakers and suggests developing and updating data-driven national dementia plans based on epidemiological data, enhancing cross-sectoral actions and preventive interventions at the population level, ensuring sustainability of community-based care, and clearly allocating financial resources for plan implementation.

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Riassunto

Analisi critica dei Piani Nazionali Demenza: confronto tra le strategie preventive di cinque Stati Europei

Introduzione. Gli interventi di prevenzione possono ridurre fino al 45% dei casi di demenza nel mondo. Lo scopo dello studio è analizzare i piani strategici nazionali di prevenzione della demenza.

Metodi. È stata condotta un'analisi comparativa qualitativa tra i piani nazionali sulla demenza dei Paesi con la migliore aspettativa di vita in buona salute degli anziani in Europa. Sono stati inclusi i piani nazionali sulla demenza di Francia, Irlanda, Italia, Spagna e Svezia. È stato valutato il consenso sulle azioni prioritarie e sugli elementi chiave delle politiche di prevenzione, in base alle raccomandazioni dell'Organizzazione Mondiale della Sanità (OMS) e a uno strumento di analisi progettato per la valutazione delle politiche sulle malattie croniche.

Risultati. Tutti i Paesi hanno sottolineato l'importanza delle politiche di prevenzione all'interno dei loro piani per la demenza e hanno istituito comitati di monitoraggio. Tuttavia, non tutti i Paesi hanno definito le scadenze per l'attuazione delle politiche e solo la Spagna ha aggiornato il proprio piano nazionale. Manca ancora l'integrazione della prevenzione delle demenze con altre campagne di prevenzione delle malattie croniche e manca anche una chiara allocazione di fondi per i piani nazionali sulla demenza.

Conclusioni. Tutti i Paesi hanno seguito ampiamente le raccomandazioni dell'OMS. Tuttavia, i piani non sono stati aggiornati. Pertanto, non affrontano tutti gli attuali fattori di rischio noti per la demenza, raccomandando la prevenzione di solo una frazione dei casi potenzialmente prevenibili. Inoltre, la necessità di un sostegno finanziario nei piani nazionali per la demenza è fondamentale ma non è stata affrontata in modo adeguato, con fonti di finanziamento incoerenti o non definite per attuare gli obiettivi.

References

1. World Health Organization (WHO). Global Health Estimates 2019. Available from: https://www.who.int/data/global-health-estimates [Last accessed: 2025 Mar 13].
2. GBD 2019 Collaborators. Global mortality from dementia: Application of a new method and results from the Global Burden of Disease Study 2019. Alzheimers Dement (N Y). 2021 Jul 27;**7**(1):e12200. doi: 10.1002/trc2.12200. PMID: 34337138; PMCID: PMC8315276.
3. GBD 2021 Nervous System Disorders Collaborators. Global, regional, and national burden of disorders affecting the nervous system, 1990-2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Neurol. 2024 Apr;**23**(4):344-81. doi: 10.1016/S1474-4422(24)00038-3. Epub 2024 Mar 14. PMID: 38493795; PMCID: PMC10949203.
4. World Health Organization (WHO). Global status report on the public health response to dementia. Geneva: World Health Organization; 2021.
5. Wu YT, Beiser AS, Breteler MMB, Fratiglioni L, Helmer C, Hendrie HC, et al. The changing prevalence and incidence of dementia over time - current evidence. Nat Rev Neurol. 2017 Jun;**13**(6):327-39. doi: 10.1038/nrneurol.2017.63. Epub 2017 May 12. PMID: 28497805.
6. GBD 2019 Dementia Forecasting Collaborators. Estimation of the global prevalence of dementia in 2019 and forecasted prevalence in 2050: an analysis for the Global Burden of Disease Study 2019. Lancet Public Health. 2022 Feb;**7**(2):e105-e25. doi: 10.1016/S2468-2667-(21)00249-8. Epub 2022 Jan 6. PMID: 34998485; PMCID: PMC8810394.
7. European Dementia Monitor 2020. Comparing and benchmarking national dementia strategies and policies. Alzheimer Europe; 2020.
8. World Health Organization (WHO), Alzheimer's Disease International (AZ), eds. Dementia: a public health priority. World Health Organization; 2012.
9. Liu KY, Walsh S, Brayne C, Merrick R, Richard E, Howard R. Evaluation of clinical benefits of treatments for Alzheimer's disease. Lancet Healthy Longev. 2023 Nov;**4**(11):e645-e51. doi: 10.1016/S2666-7568(23)00193-9. PMID: 37924845.
10. National Academies of Sciences, Engineering, and Medicine; Division of Behavioral and Social Sciences and Education; Board on Behavioral, Cognitive, and Sensory Sciences; Committee on the Decadal Survey of Behavioral and Social Science Research on Alzheimer's Disease and Alzheimer's Disease-Related Dementias. Reducing the Impact of Dementia in America: A Decadal Survey of the Behavioral and Social Sciences. Washington (DC): National Academies Press (US); 2021 Jul 26. PMID: 34613684.
11. Blandi L, Bertuccio P, Amorosi A, Clemens T, Brand H, Odone A. 20-Year trends of hospitalisation among people with dementia: a region-wide retrospective cohort study from Lombardy, Italy. Public Health. 2023 Sep;**222**:21-8. doi: 10.1016/j.puhe.2023.06.036. Epub 2023 Jul 25. PMID: 37499438.
12. Livingston G, Sommerlad A, Orgeta V, Costafreda SG, Huntley J, Ames D, et al. Dementia prevention, intervention, and care. Lancet. 2017 Dec 16;**390**(10113):2673-734. doi: 10.1016/S0140-6736(17)31363-6. Epub 2017 Jul 20. PMID: 28735855.
13. Livingston G, Huntley J, Sommerlad A, Ames D, Ballard C, Banerjee S, et al. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. Lancet. 2020 Aug 8;**396**(10248):413-46. doi: 10.1016/S0140-6736-(20)30367-6. Epub 2020 Jul 30. PMID: 32738937; PMCID: PMC7392084.
14. Livingston G, Huntley J, Liu YK, Costafreda GS, Selbæk G, Alladi S, et al. Dementia prevention, intervention, and care: 2024 report of the Lancet standing Commission. The Lancet. 2024 Aug 10;**404**(10452):572-628. doi: 10.1016/S0140-

6736(24)01296-0. Epub 2024 Jul 31. PMID: 39096926.
15. Jørgensen K, Nielsen TR, Nielsen A, Waldemar G. Potential for prevention of dementia in Denmark. Alzheimers Dement. 2023 Oct;**19**(10):4590-8. doi: 10.1002/alz.13030. Epub 2023 Mar 18. PMID: 36933232.
16. Mukadam N, Sommerlad A, Huntley J, Livingston G. Population attributable fractions for risk factors for dementia in low-income and middle-income countries: an analysis using cross-sectional survey data. Lancet Glob Health. 2019 May;**7**(5):e596-e603. doi: 10.1016/S2214-109X(19)30074-9. PMID: 31000129; PMCID: PMC7617123.
17. Rose G. Sick individuals and sick populations. Int J Epidemiol. 2001 Jun;**30**(3):427-32; discussion 33-4. doi: 10.1093/ije/30.3.427. PMID: 11416056.
18. World Health Organization (WHO). Risk reduction of cognitive decline and dementia: WHO guidelines. World Health Organization; 2019.
19. Frisoni GB, Altomare D, Ribaldi F, Villain N, Brayne C, Mukadam N, et al. Dementia prevention in memory clinics: recommendations from the European task force for brain health services. Lancet Reg Health Eur. 2023 Jan 31;**26**:100576. doi: 10.1016/j.lanepe.2022.100576. PMID: 36895446; PMCID: PMC9989648.
20. World Health Organization (WHO). Global action plan on the public health response to dementia 2017–2025. World Health Organization; 2017.
21. Kane H, Lewis MA, Williams PA, Kahwati LC. Using qualitative comparative analysis to understand and quantify translation and implementation. Transl Behav Med. 2014 Jun;**4**(2):201-8. doi: 10.1007/s13142-014-0251-6. PMID: 24904704; PMCID: PMC4041929.
22. World Health Organization (WHO). Healthy life expectancy (HALE) at 60 (years). World Health Organization; 2020. Available from: https://www.who.int/data/gho/data/indicators/indicator-details/GHO/gho-ghe-hale-healthy-life-expectancy-at-age-60 [Last accessed: 2025 Mar 13].
23. Cheung KK, Mirzaei M, Leeder S. Health policy analysis: a tool to evaluate in policy documents the alignment between policy statements and intended outcomes. Aust Health Rev. 2010;**34**(4):405-13.
24. Esser F, Vliegenthart R. Comparative Research Methods. In: Matthes J, Davis CS, eds. The International Encyclopedia of Communication Research Methods. London: Wiley-Blackwell; 2017: 248-269.
25. Collins R, Silarova B, Clare L. Dementia Primary Prevention Policies and Strategies and Their Local Implementation: A Scoping Review Using England as a Case Study. J Alzheimers Dis. 2019;**70**(s1):S303-S18. doi: 10.3233/JAD-180608. PMID: 30507574; PMCID: PMC6700624.
26. Relkin N. Screening and early diagnosis of dementia. Am J Manag Care. 2000 Dec;**6**(22 Suppl):S1111-8; discussion S9-24. PMID: 11142176.
27. Ranson JM, Kuźma E, Hamilton W, Lang I, Llewellyn DJ. Case-finding in clinical practice: An appropriate strategy for dementia identification? Alzheimers Dement (N Y). 2018 Jul 10;**4**:288-96. doi: 10.1016/j.trci.2018.04.011. PMID: 30090849; PMCID: PMC6077836.
28. National Institute for Health and Care Excellence (NICE). Guidelines. Dementia: assessment, management and support for people living with dementia and their carers. NICE; 2018.
29. Istituto Superiore di Sanità (ISS). Diagnosi e trattamento di demenza e Mild Cognitive Impairment - Italian Guidelines. Rome: Istituto Superiore di Sanità; 2024.
30. van den Dungen P, Moll van Charante EP, van de Ven PM, van Marwijk HW, van der Horst HE, van Hout HP. Case Finding of Mild Cognitive Impairment and Dementia and Subsequent Care; Results of a Cluster RCT in Primary Care. PLoS One. 2016 Jun 16;**11**(6):e0156958. doi: 10.1371/journal.pone.0156958. PMID: 27310616; PMCID: PMC4910994.
31. Bressan V, Visintini C, Palese A. What do family caregivers of people with dementia need? A mixed-method systematic review. Health Soc Care Community. 2020 Nov;**28**(6):1942-60. doi: 10.1111/hsc.13048. Epub 2020 Jun 16. PMID: 32542963.
32. Jackson GA, Browner D. Supporting carers of people with dementia: what is effective? BJPsych Advances. 2017;**23**:179-86. doi:10.1192/apt.bp.113.011288.
33. Lanza TE, Paladini A, Marziali E, Gianfredi V, Blandi L, Signorelli C, et al. Training needs assessment of European frontline health care workers on vaccinology and vaccine acceptance: a systematic review. Eur J Public Health. 2023 Aug 1;**33**(4):591-5. doi: 10.1093/eurpub/ckad101. PMID: 37348861; PMCID: PMC10393484.
34. Religa D, Fereshtehnejad SM, Cermakova P, Edlund AK, Garcia-Ptacek S, Granqvist N, et al. SveDem, the Swedish Dementia Registry - a tool for improving the quality of diagnostics, treatment and care of dementia patients in clinical practice. PLoS One Feb 19. 2015;**10**(2):e0116538. doi: 10.1371/journal.pone.0116538. PMID: 25695768; PMCID: PMC4335024.
35. Bacigalupo I, Giaquinto F, Salvi E, Carnevale G, Vaccaro R, Matascioli F, et al. A new national survey of centers for cognitive disorders and dementias in Italy. Neurol Sci. 2024 Feb;**45**(2):525-38. doi: 10.1007/s10072-023-06958-8. Epub 2023 Aug 18. PMID: 37592124; PMCID: PMC10791890.
36. Machluf Y, Tal O, Navon A, Chaiter Y. From Population Databases to Research and Informed Health Decisions and Policy. Front Public Health. 2017 Sep 21;**5**:230. doi: 10.3389/fpubh.2017.00230. PMID: 28983476; PMCID: PMC5613084.
37. Cashin C. Health Financing Policy: The Macroeconomic, Fiscal, and Public Finance Context. Washington, DC: World Bank; 2016.
38. Morton T, Wong G, Atkinson T, Brooker D. Sustaining community-based interventions for people affected by dementia long term: the SCI-Dem realist review. BMJ Open. 2021 Jul 7;**11**(7):e047789. doi: 10.1136/bmjopen-2020-047789. PMID: 34233990; PMCID: PMC8264885.
39. Blandi L, Bertuccio P, Clemens T, Brand H, Odone A. Incidence and mortality trends of people living with dementia among 7 million individuals over 10 years in Italy: A ret-

rospective cohort study using administrative linked data. Ann Epidemiol. 2025 Mar 12;**104**:72-78. doi: 10.1016/j.annepidem.2025.03.007. Epub ahead of print. PMID: 40086677.

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Supplementary material 1

Scoping review

I. Aim

This study aims to review evidence on the action-oriented frameworks relevant to dementia prevention policies.

II. Methods

IIA. Definition

The "framework" is a document (or model or structure) to guide the development and implementation of actions, plans and policies to reduce risks of dementia and/or improve outcomes for people living with dementia. The "action-oriented framework" is defined as a framework which focus on decision or policy-making processes. It can support policymakers, researchers, and practitioners in taking action on the social determinants of health by identifying requirements for action and entry points for intervention. It can also help identify priority issues and evaluate the potential success of interventions by allowing for the possibility of modeling interventions.

IIB. Inclusion criteria

National level frameworks, i.e. Dementia care guidelines/policies/strategies (and must not be specific to Alzheimer's Disease only);

Guidelines/frameworks/strategies licensed by governmental bodies or a national organizations which are legally able to be translated into practice;

Document available in English.

IIC. Sources of information

Guidelines/frameworks/strategies are from:
A government body or national organization
Non-Governmental Organizations (NGOs)
Scientific literature (PubMed, Embase)
Grey literature (selected websites from a list of institutions)

IID. Search strategies

PubMed

((Guidelin*[Title/Abstract]) OR ("Guidelines as topic"[MeSH Terms]) OR ("Policy"[MeSH Terms]) OR (Polic*[Title/Abstract]) OR (Program*[Title/Abstract]) OR ("Program development"[MeSH Terms]) OR (Strateg*[Title/Abstract]) OR (Framework* [Title/Abstract])) AND (("Alzheimer Disease/Prevention and control"[MeSH Terms]) OR ("Dementia, multi infarct/Prevention and control"[MeSH Terms]) OR ("Dementia, vascular/Prevention and control"[MeSH Terms]))

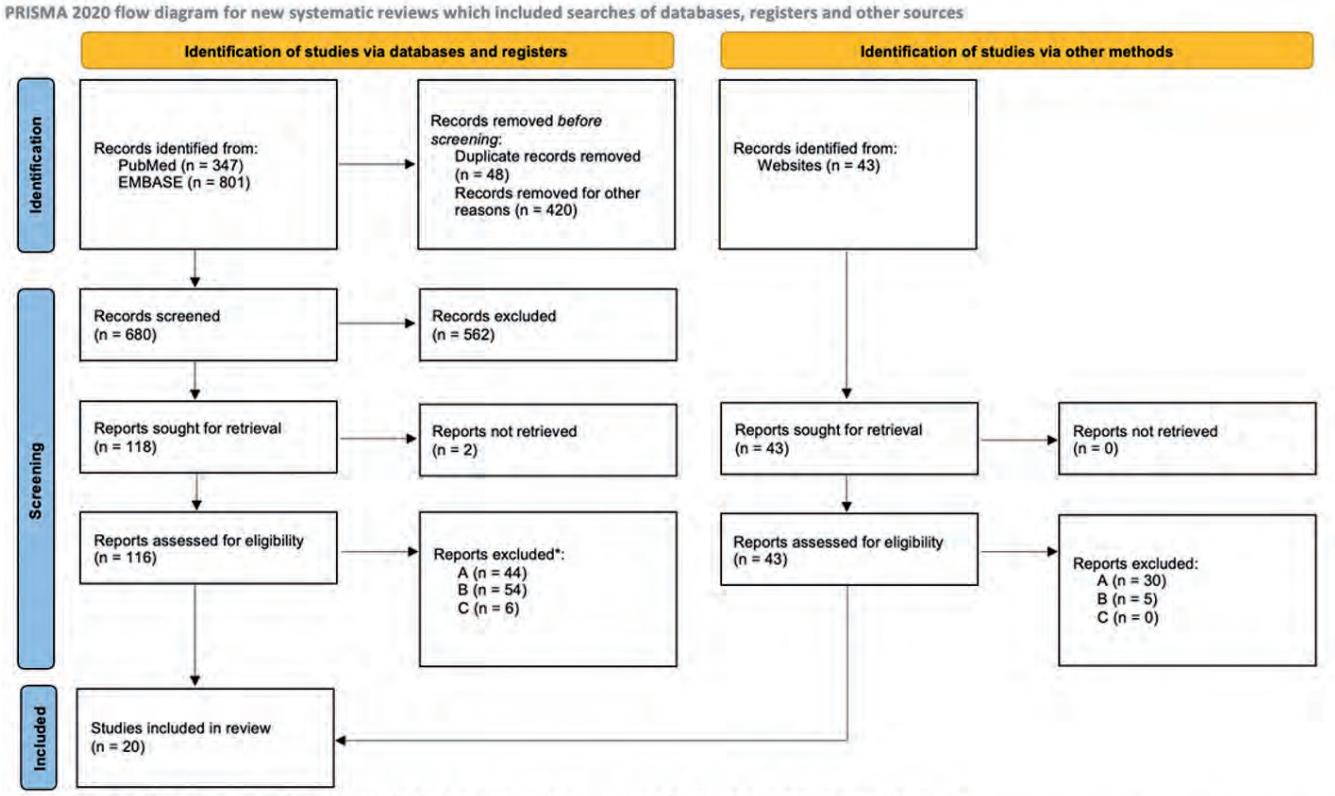
Embase

Guidelin* OR 'Guidelines' OR Policy OR Polic* OR Program* OR Program development OR Strateg* OR Framework* AND Alzheimer Disease/Prevention and control OR Dementia, multi infarct/Prevention and control OR Dementia, vascular/Prevention and control

Selected websites

Institution	Website	Zone
Scientific Institute of Public Health	https://www.sciensano.be/en	Belgium
Canadian Institutes of Health Research	https://cihr-irsc.gc.ca/e/193.html	Canada
European Centre for Disease Prevention and Control	https://www.ecdc.europa.eu/en	Europe
European Prevention of Alzheimer's Dementia Consortium	https://ep-ad.org/	Europe
Alzheimer Europe	https://www.alzheimer-europe.org/	Europe
Institut Pasteur	https://www.pasteur.fr/en	France
Haute Autorité de santé	https://www.has-sante.fr/	France
Robert Koch Institute	https://www.rki.de/EN/Home/homepage_node.html	Germany
The Alzheimer Society of Ireland	https://alzheimer.ie/	Ireland
Istituto Superiore di Sanità	https://www.iss.it/	Italy
National Institute for Public Health and the Environment	https://www.rivm.nl/en	Netherlands
Instituto de Salud Carlos III	https://eng.isciii.es/eng.isciii.es/Paginas/Inicio.html	Spain
Karolinska Institutet	https://ki.se/en	Sweden
Swiss Tropical and Public Health Institute	https://www.swisstph.ch/en/	Switzerland
National Health System	https://www.nhs.uk/	UK
Alzheimer's Society	https://www.alzheimers.org.uk/	UK
Centers for Disease Control and Prevention	https://www.cdc.gov/	USA
Alzheimer's Foundation of America	https://alzfdn.org/	USA
National Institute of Health	https://www.nih.gov/	USA
Alzheimer.gov	https://www.alzheimers.gov/	USA
National Institute on Aging	https://www.nia.nih.gov/	USA
World Health Organization	https://www.who.int/	World
UNICEF	https://www.unicef.org/	World
Alzheimer Association	https://www.alz.org/	World
Alzheimer's Disease Internation	https://www.alzint.org/	World

III. Results



*(A) Not "action-oriented" document; (B) Not comprehensive prevention policies to recommend at national level; (C) Language not included

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

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Measuring Health Literacy among seniors: validation of the European Health Literacy Survey Questionnaire 6 in the Tuscan PASSI sample

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Keywords: Health literacy; HLS-EU-Q6; validation process; older adults; seniors
Parole chiave: Alfabetizzazione sanitaria; HLS-EU-Q6; processo di validazione; anziani

Abstract

Background*. The demographic transition has led to an increase in the older population, resulting in a rise in individuals with comorbidities and reduced self-sufficiency. Low health literacy levels are associated with poor health outcomes especially among vulnerable groups (like older individuals). Enhancing health literacy through targeted programs is crucial for improving self-care in chronic conditions. To date, in Italy, there are no validated tools to measure health literacy in older people. Thus, the aim of this study is to validate the European Health Literacy Survey Questionnaire 6 in a Tuscan (Italy) sample of senior individuals.*
Study design. *Cross-sectional.*
Methods. *The sample was drawn from the Surveillance System of Advancements in health of the Italian Local Healthcare Units from 2017 to 2019. Item analysis, Cronbach's alpha and confirmatory factor analysis were used to validate the scale. Additionally, associations between Health Literacy levels and sociodemographic characteristics were analyzed.*
Results*. A total of 11,000 subjects were interviewed, with 1,080 (10%) aged 65-69. Cronbach's alpha was 0.89. In the older subgroup, the percentage of missing responses ranged from 4.54% to 11.85%, with the fourth item having the highest percentage of missing values. The confirmatory factor analysis revealed that the three-factor model showed a better fit to the data compared to the unidimensional model. Similar findings were observed in the 18-65-year-old population. In both groups, individuals with economic difficulties or lower education were at higher risk of having inadequate levels of health literacy. Moreover, in the 18-64 age group, being female reduced the probability of having an inadequate health literacy level, while being inactive/retired or a foreigner increased it.*
Conclusions*. The study provides preliminary evidence supporting the validity and reliability of the European Health Literacy Survey Questionnaire 6 for assessing health literacy in the Italian older population. Further research is necessary to confirm these findings, particularly in samples of individuals aged over 69 years.*

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Introduction

According to the World Health Organization (WHO), between 2000 and 2050, the population over 65 years old is expected to double (1). The 2022 Annual Report of Italian Statistics confirmed that Italy remains one of the world's oldest countries (2), with Tuscany being one of its oldest regions, with an aging index (the percentage ratio between the population aged 65 and over and the population aged 0-14) increased from 211.4 in 2019 to 214.6 in 2020 (3). While the rise in longevity is one of the most remarkable achievements in human history, increased lifespan is not necessarily synonymous with healthy aging (1).

The demographic transition has led to an increase in the older population and, consequently, in the proportion of non-self-sufficient individuals affected by one or multiple chronic diseases (4). Older patients may be required to manage their complex health conditions within a context marked by the weakening of family and social support networks.

Among the determinants of health, even in old age, health literacy (HL) holds a significant place (5,6). HL has been defined by Sørensen et al. as a multidimensional concept that refers to individual's knowledge, motivation, and skills to access, understand, evaluate, and apply health information in order to make decisions regarding healthcare, disease prevention, and health promotion to maintain or improve quality of life throughout their lifespan (7).

Many studies indicate that socioeconomic status, race, cognitive abilities, educational attainment, and age can impact HL levels. Lower HL levels are associated with adverse health outcomes, increased unhealthy behaviors, reduced utilization of preventive healthcare services, and higher drug consumption (8,9). These effects are even more pronounced among older individuals, as cognitive impairments may hinder understanding and processing of new information, resulting in lower HL (10,11).

Therefore, investing in programs that enhance HL in this vulnerable population segment is key to improving self-care in chronic conditions, providing individuals with effective resources for helping them better manage their health (12).

The first step toward achieving this goal is to ensure that adequate instruments are available to measure HL in this target population. A review of the literature from 1993 to 2021, identified 151 HL measurement instruments: 39 were general health literacy instruments, 90 condition specific (disease or content), and 22 were populations-specific (13). Among those 22, only two focused on older people (a Korean and a Taiwanese scale). Therefore, the review revealed that, while there are validated tools for this target in clinical settings, none exist for the general older adult population. The review also highlights the European Health Literacy Survey Questionnaire (HLS-EU-Q), in its various versions, as one of the most widely used instruments in Europe with potential for universal application. Thus, the purpose of our study is to evaluate the psychometric properties of the HLS-EU-Q6, previously validated in Italian language (14), in a sample of older individuals, aged 65 to 69, within the PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia) surveillance system, in Tuscany.

Materials and Methods

Since 2008, PASSI has been collecting data on the prevalence of some major modifiable risk factors among the adult population living in Italy (15-17). This system involves Local Health Units (LHUs) under the supervision and coordination of the Italian National Institute of Health, known as the Istituto Superiore di Sanità (ISS), that ensure technical-scientific support and methodological rigor in every phase of the survey. PASSI implements the "behavioral risk factor surveillance" (BRFS) model, developed by the US Centers for Disease Control and Prevention (18).

The BRFS approach focuses on near-continuous data collection and aims to support health promotion and public health decision-making by providing relevant information on behavioral risk factors. To gather this information, a standardized questionnaire is used, consisting of over one hundred questions grouped into 12 modules. These modules investigate the lifestyles of adults aged 18 to 69 and their adherence to preventive measures and programs.

Over the years, additional modules have been proposed by various regions or institutions such as ministries or universities to address specific public health information needs. One such example is the introduction of a module to measure HL in 2017 (19,20). This module was added to the core PASSI questionnaire administered to the Tuscan population, building on experiences from other countries with similar surveillance systems or health surveys.

The inclusion of the HL module reflects the growing importance of HL in addressing public health challenges. By collecting data on HL levels, PASSI can provide valuable insights into the population's ability to access, understand, and utilize health

information. This data can inform the development of targeted health promotion strategies and interventions to improve health outcomes in Italy.

Study population, sampling criteria and data collection

Data was collected between 2017 and 2019 from a population-based sample of the PASSI system in Tuscany. In each participating LHU, a monthly random sample was drawn from the list of residents aged 18 to 69, stratified by gender and age to be proportional to the distribution in the general population. Exclusion criteria were unavailability of a phone number, inability to communicate in Italian, and being institutionalized during the survey period.

Once the sample had been selected, individuals were sent a letter outlining the purpose of the surveillance system and personal data processing. The letter invited individuals to provide the phone number where they wished to be contacted to schedule the interview or, alternatively, to express their refusal to participate. Trained personnel from the public health departments of each LHU conducted the interviews, with the option to use the CATI (computer-assisted telephone interview) method. To ensure contact, a minimum of six attempts were made on different days of the week, including weekends, and at various times throughout the day. If a person could not be reached, a replacement from the same gender and age group was randomly chosen. Since the interviews were conducted by phone, obtaining and storing the consent for personal data processing was not feasible. Afterward, the data were anonymized and electronically stored in a national database, and interviews conducted throughout each calendar year were then compiled into an annual dataset.

Measures

Data collection included socio-demographic determinants, such as gender (male or female), age, which we categorized as "adults" (18-64 years) and "young seniors" (over 65 years), education level, which was dichotomized into "low" (secondary school diploma or lower) and "high" (high school diploma or higher). Nationality (Italian or foreign) and occupational status were also recorded, with the latter divided into three categories: employed, looking for work, and inactive. Finally, financial status was assessed by asking respondents about their ability to manage personal or familial financial resources at the end of the month; responses were grouped into "good" (comprising "very easily" and "quite easily") and "poor" (consisting of "with some difficulties" and "with many difficulties") for analytical purposes.

The HL level of participants was assessed using the HLS-EU-Q6, a shortened version of the HLS-EU-Q47 questionnaire, developed by selecting 6 items and already used both in general and specific populations (14,21). The HLS-EU-Q6 is a self-reported tool with Likert-type responses, where participants indicate their perceived ease or difficulty in understanding (item 1), appraising (item 2), accessing (item 3) health-related information and applying (item 4,5,6) the knowledge gained to address or solve a health problem. The response options are: "very easy," "fairly easy," "fairly difficult," and "very difficult." Each response option is assigned a score: "very easy" = 4, "fairly easy" = 3, "fairly difficult" = 2, and "very difficult" = 1. Response of "don't know" or refusal to answer was recorded as missing, as suggested by other authors (22,14). To calculate the final scale score for each participant, the mean value of their responses is computed. The scale score can range from 1 to 4, with higher scores indicating better HL. To be included in the analysis, respondents had to answer at least five of the six items. Based on the final scale scores, the following levels of HL are defined: Inadequate HL ($1 \leq x \leq 2$); Problematic HL ($2 < x < 3$); Sufficient HL ($3 \leq x \leq 4$).

Statistical analysis

We divided our sample into 2 subgroups: the first consisting of adults aged 18-64 and the second consisting of young seniors aged 65-69. For each subgroup we proceeded with the HLS-EU-Q6 scale evaluation. First, we performed item analysis to examine the distribution of the responses, determine the percentage of missing items (that is, a proxy of item difficulties and comprehensibility) and assess the presence of ceiling or floor effects (i.e., limits in variability due to an excess of at least 20% of responses in the highest or lowest category, respectively). Second, we tested reliability using Cronbach's α. Third, we explored the dimensional structure of the HLS-EU-Q6 using confirmatory factor analysis (CFA). Three models were fitted: a one-factor model, a three-factor model according to the 3 domains of the HLS-EU-Q6 - health promotion (items 1 and 2), disease prevention (items 3 and 4) and health care (items 5 and 6) - and a two-order model theorized by Pelikan et al. (23). Fit indices used included the comparative fit index (CFI) and Tucker-Lewis index (TLI), with a good fit indicated by values >0.95, a poor fit by values <0.90, and acceptable fit falling between these thresholds. The

root mean square error approximation (RMSEA) was also used, with a good fit indicated by values <0.06, a poor fit by values >0.10, and an acceptable fit by values in between (24). Finally, to assess the convergent and discriminant validity of the HLS-EU-Q6, a multivariate logistic regression model was created for each subgroup to investigate predictors of inadequate HL levels. According to literature, lower HL was expected to be predicted by lower education levels, poorer perceived financial situations, unemployment, and foreign nationality (25-27). For each analysis, an alpha level of 0.05 was considered significant. The analyses were conducted using STATA 18 Now.

Results

Sample description

A total of 11,000 subjects were interviewed by PASSI Surveillance System in the Tuscany region. Of these, 9,654 were aged 18-64 (49.04% male; 42.17% with poor economic status; 28.01% with low educational attainments; 28.55% not employed; 7.52% with foreign citizenship) and 1,080 were aged 65 and older (51.36% male; 41.23% with poor economic status; 53.76% with low education level; 2.22% with foreign citizenship). Both age groups had comparable levels of HL. Specifically, 64.21% of adults and 56.51% of young seniors had sufficient HL, 27.49% and 30.21% faced problematic HL and 8.30% and 13.28% had inadequate HL, achieving a total average score of 2.07 (SD 0.53) and of 2.21 (SD 0.56), respectively (Table 1). Considering the mean HL scores within each domain - healthcare, disease prevention and health promotion - similar values were observed between the two groups: 2.04, 2.16 and 2.03 respectively in the adult group and 2.11, 2.32 and 2.19 in the young senior group.

Item analysis

Table 2 reports the item responses. The percentage of missing responses ranged from 3.21% to 8.66% for adult respondents, and from 4.54% to 11.85% for young seniors. For both subgroups, the highest percentage of missing values was for the third item: “Find information on how to manage mental health problems like stress or depression”. Neither ceiling nor floor effects were observed.

Table 1 - Sample characteristics.

Variables	Age (years)			
	18-64 (N=9,654)		65+ (N=1,080)	
	%	CI	%	CI
Gender				
Male	49.04	48.63 - 49.46	51.36	48.71 - 54
Female	50.96	50.54 - 51.37	48.64	46.0 - 51.29
Education				
High	71.99	71.08 - 72.88	46.24	43.24 - 49.26
Low	28.01	27.12 - 28.92	53.76	50.74 - 56.76
Nationality				
Italian	92.48	91.91 – 93.0	97.77	96.63 - 98.53
Foreign	7.52	6.99 - 8.09	2.22	1.47 - 3.37
Financial status				
Poor	42.17	41.16 - 43.18	41.23	38.26 - 44.26
Good	57.83	56.82 - 58.84	58.77	55.74 - 61.74
Employment status				
Employed	71.45	70.57 - 72.32	14.44	12.45 - 16.69
Looking for work	7.68	7.16 - 8.23	0.57	.25 - 1.23
Inactive	20.87	20.08 - 21.67	84.99	82.71 - 87.01
Health Literacy				
Inadequate	8.3	7.73 – 8.9	13.28	11.24 – 15.62
Problematic	27.49	26.55 – 28.46	30.21	27.34 – 33.25
Sufficient	64.21	63.18 – 65.22	56.51	53.3 – 59.66

Table 2. Percentages of item responses for HLS-EU-Q6.

Domains	ITEM	18-64 (n. 9654)						65+ (n. 1080)					
		Very difficult	Fairly difficult	Fairly Easy	Very easy	Missing	Domain mean	Very difficult	Fairly Difficult	Fairly Easy	Very easy	Missing	Domain mean
Health promotion	1. Understand information in the media on how to get healthier?	16.88	64.59	12.45	2.86	3.21	2.03	10.19	61.76	17.59	4.63	5.83	2.19
	2. Find out about activities that are good for your mental well-being?	16.05	59.96	14.91	3.19	5.89		10.28	57.59	18.80	5.74	7.59	
Disease prevention	3. Judge if the information on health risks in the media is reliable?	11.90	59.70	20.39	4.11	3.91	2.16	7.50	53.24	25.46	6.57	7.22	2.32
	4. Find information on how to manage mental health problems like stress or depression?	11.87	56.69	18.41	4.37	8.66		6.76	52.31	22.69	6.39	11.85	
Healthcare	5. Use information the doctor gives you to make decisions about your illness?	17.03	64.35	12.40	2.21	4.02	2.04	14.26	64.07	14.44	2.69	4.54	2.11
	6. Judge when you may need to get a second opinion from another doctor?	14.46	58.06	18.07	3.41	6.01		11.67	58.61	19.07	4.07	6.57	

Reliability and confirmatory factor analysis (CFA)

Cronbach's alpha coefficients for the adult and young senior questionnaires were calculated to assess internal consistency, yielding values of 0.88 and 0.89, respectively (Table 3). These results indicate a high level of reliability for both subgroups.

The results indicated that for both subgroups, the three-factor model provided a better fit to the data than the unidimensional model (Table 4). However, computational issues (specifically, a non-positive information matrix) precluded a reliable assessment of fit indices for the two-order CFA model.

According to the multivariate logistic regression analysis, both subgroups with good economic status and higher education levels had significantly lower adjusted odds ratios for inadequate HL levels. Conversely, being a foreign citizen significantly increased the likelihood of having inadequate HL. Additionally, in the 18-64 population, being female reduced the likelihood of inadequate HL, while being unemployed or retired increased the likelihood of having an inadequate HL (Table 5).

Table 3 - Reliability by item and age group.

		18-64		65+	
		Cronbach's Alpha	Covariance	Cronbach's Alpha	Covariance
Test (all items)		0.88	0.25	0.90	0.29
Excluded Item	1. Understand	0.86	0.26	0.88	0.29
	2. Find out	0.86	0.25	0.88	0.28
	3. Judge	0.86	0.25	0.88	0.28
	4. Find	0.85	0.24	0.87	0.27
	5. Use	0.87	0.27	0.89	0.30
	6. Judge a second opinion	0.87	0.26	0.89	0.30

Table 4 - Fit statistics of the confirmatory factor analysis.

Fit Statistics	18-64		65+	
	1 Factor Model	3 Factors Model	1 Factor Model	3 Factors Model
Chi2	1837.168	808.678	238.688	63.433
RMSEA (90% CI)	0.157 (0.151-0.163)	0.127 (0.120-0.130)	0.171 (0.152-0.190)	0.105 (0.082-0.129)
SRMR	0.047	0.026	0.050	0.020
CFI	0.929	0.969	0.929	0.982
TLI	0.882	0.922	0.881	0.956

Table 5 - Multiple logistic regression analysis: association of sociodemographic factors with inadequate HL.

Variables	18-64				65+			
	Adjusted Odds Ratio	P	[95% Conf. Interval]		Adjusted Odds Ratio	P	[95% Conf. Interval]	
Gender								
Female	0.79	0.00	0.67	0.93	1.02	0.90	0.69	1.50
Financial status								
Good	0.39	0.00	0.33	0.47	0.49	0.00	0.33	0.74
Employment status								
Unemployed	1.30	0.04	1.00	1.67	2.82	0.28	0.42	1.90
Inactive/retired	1.29	0.00	1.07	1.56	1.35	0.32	0.73	2.51
Education								
High	0.52	0.00	0.44	0.61	0.57	0.01	0.37	0.88
Nationality								
Foreign	3.24	0.00	2.64	3.99	3.89	0.00	1.46	10.35

Discussion

The psychometric properties of measurement tools are generally sample- and population-dependent (28). Given the absence of a psychometric evaluation of the HLS-EU-Q6 among seniors, this study aimed to demonstrate its suitability and applicability for use in this specific population from a public health perspective.

According to our findings, in the two age groups: (i) HL levels differed but not by a large margin; (ii) the distribution of responses and the psychometric properties of the HLS-EU-Q6 (structural model, reliability, convergent, and discriminant validity) were largely similar between the two groups, with few exceptions.

Particularly, while neither group showed a ceiling or floor effect, the percentage of missing items was slightly higher in the young senior group. In line with the results of the EU survey (29) and other studies (14,30), one of the items related to mental health ("Find information on how to manage mental health problems like stress or depression?") showed the highest percentage of "don't know/ refuse" responses in both age groups. This could be due, in part, to respondents' unfamiliarity with mental health problems and, on the other hand, to the stigma still associated with these conditions, which induces people to keep them hidden for fear of judgment (31). The HLS_{19} International Report of Measuring Population and Organizational Health Literacy (M-POHL) network identified a specific recommendation on this issue (Recommendations 6), in fact "Supporting mental HL in the fields of promotion and prevention may help reduce the burden of disease in this field. Mental HL around treatment may encourage people to seek treatment in a timely way and add to the effectiveness of services" (29).

Particularly, the HLS-EU-Q6 showed good internal validity in both subgroups with a Cronbach's alpha of 0.90 for young seniors and 0.88 for adults. This was in line with the original scale (21) and other validation studies conducted in Europe, which reported values between $\alpha = 0.80$ and $\alpha = 0.98$ (14,32-38).

In both subgroups, CFA suggested that the three-factor structure, comprising health promotion, disease prevention and healthcare domains, fit better than the unidimensional model. However, we were unable to estimate the fit of a two-order CFA model, theorized by Pelikan et al. (23), due to computational issues.

Concerning HL levels, our results are in line with those of other studies conducted in Europe that used the HLS-EU-Q16 to measure HL in the general population. For example, in Poland, results from a research in a nationally representative sample of the Polish general adult population (18 years or older) showed that 10.2% had inadequate HL, 34.4% had problematic HL, and 55.4% had a sufficient level of HL (39). In Romania, findings from a similar sample "show that most of the participants (59.2%) have a sufficient level of HL, while 33.2% have a problematic level and 7.5% an inadequate level of HL" (30). A large study conducted in Denmark among adults aged ≥25 years reported 60.9% sufficient HL, 30.9% problematic HL and 8.2% inadequate HL (40). As expected, a higher percentage of inadequate HL level can be observed in the young senior group (13.3% vs 8.3%), despite their age being relatively close to the adult group. Research indicates that older adults often exhibit lower HL levels (41,42). Cognitive decline, prevalent in older populations, further exacerbates this issue, as it is a key factor driving the inverse relationship between age and HL (42). A 2018 German study (43), using HLS-EU-Q47 to investigate HL among older adults (aged 65 years or above), stratified by age groups, showed that inadequate HL was nearly three times more prevalent in the oldest age group, consistent with our findings. Additionally, older adults are at a higher risk of inadequate HL due to factors such as education and socioeconomic status (44).

As described in the European survey (9), confirmed in the HLS_{19} (29), and reported in other key studies (45), a social gradient for HL exists and has also been observed in our study, confirming the external validity of the HLS-EU-Q6 for both age subsets. However, we found differences regarding gender and employment status. A significant positive association between HL and female gender was observed in the adult group but not in the young senior group. Women were less likely to have limited HL, which is consistent with the HLS_{19} findings, where "men tend to have slightly lower health literacy". However, other studies have found no significant gender differences in HL (9,46-49), and the relationship between gender and HL remains a topic of debate. Consequently, it is difficult to explain these results, and we currently lack a theory to interpret them. Finally, regarding employment status, logistic regression analysis showed that being inactive or unemployed were positively associated with limited HL, though this association was only statistically significant in the adult group. This is somewhat expected due to the differences in the job market between younger and older adults. While employment can significantly influence the socioeconomic status

of an adult (50), for seniors, being employed loses its predictive significance (51). Based on the results of this study, we can conclude that the HLS-EU-Q6 instrument is suitable for measuring health literacy in the general older population belonging to the 65-69 age group.

The main limitation of this study is the age range of the young senior sample, which includes individuals aged 65 to 69 years (as the PASSI system covers a population aged 18 to 69 years). This range focuses on older adults who are generally in good health and-hopefully-in a pre-fragility stage, where health promotion interventions are still feasible. Future research should explore the instrument's validity in older segments of the population.

The study's main strength is its large, representative sample of the Italian population, along with its rigorous study design.

Conclusions

The results of the study provide initial support for the validity and reliability of the HLS-EU-Q6 questionnaire among Italian older adults. Although the sample size is relatively large, it is not fully representative of the entire older population, due to the age limit of 69 years; therefore, further research is needed to confirm these findings. For instance, integrating this HL module into the PASSI d'ARGENTO surveillance system (52), which includes individuals aged 65 and older but does not currently assess this dimension, would facilitate broader generalization of the results. Assessing health literacy is crucial for understanding the needs of both the general and vulnerable population subgroups, identifying their potential difficulties in interacting with health services, while providing information to design-and-plan-appropriate health interventions.

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Riassunto

Misurare l'alfabetizzazione sanitaria negli anziani: validazione dello European Health Literacy Survey Questionnaire 6 nel campione toscano di PASSI

Introduzione. La transizione demografica ha portato a un aumento della popolazione anziana, con un conseguente incremento di individui con comorbilità e ridotta autosufficienza. Bassi livelli di alfabetizzazione sanitaria sono associati a esiti negativi per la salute, soprattutto tra i gruppi vulnerabili (come gli anziani). Migliorare l'alfabetizzazione sanitaria attraverso programmi mirati è fondamentale per migliorare l'autogestione delle condizioni croniche. Attualmente, in Italia non esistono strumenti validati per misurare l'alfabetizzazione sanitaria nella popolazione anziana italiana, pertanto lo scopo di questo studio è validare il Questionario 6 per la Sorveglianza Europea dell'Alfabetizzazione Sanitaria in un campione di anziani toscani.

Disegno di studio. Trasversale.

Metodi. Il campione è stato selezionato dal sistema di sorveglianza "Progressi delle Aziende Sanitarie per la Salute in Italia" nel triennio 2017-2019. Per validare la scala sono stati utilizzati l'analisi degli item, l'alfa di Cronbach e l'analisi fattoriale confermativa. Inoltre, sono state analizzate le associazioni tra livelli di alfabetizzazione sanitaria e caratteristiche socio-demografiche.

Risultati. Sono stati intervistati 11.000 soggetti, di cui 1.080 (10%) di età compresa tra 65 e 69 anni. L'alfa di Cronbach è risultata pari a 0,89. Tra gli anziani, la percentuale di risposte mancanti variava dal 4,54% all'11,85%, con il quarto item che mostrava la percentuale più alta di valori mancanti. L'analisi fattoriale confermativa ha rivelato che il modello a tre fattori mostrava un miglior adattamento ai dati rispetto al modello unidimensionale. Risultati simili sono emersi nella popolazione di 18-64 anni. In entrambi i gruppi, le persone con difficoltà economiche o con un basso livello di istruzione erano maggiormente a rischio di avere un livello inadeguato di alfabetizzazione sanitaria. Inoltre, nel gruppo 18-64 anni, il sesso femminile riduceva la probabilità di un livello inadeguato di alfabetizzazione sanitaria, mentre essere inattivi/pensionati o stranieri ne aumentava la probabilità.

Conclusioni. Lo studio fornisce evidenze preliminari a supporto della validità e dell'affidabilità del Questionario 6 per la Sorveglianza Europea dell'Alfabetizzazione Sanitaria, per valutare l'alfabetizzazione sanitaria nella popolazione anziana italiana. Sono necessarie ulteriori ricerche per confermare questi risultati, in particolare su campioni di individui di età superiore ai 69 anni.

References

1. Beard JR, Officer A, De Carvalho IA, Sadana R, Pot AM, Michel JP, et al. The World report on ageing and health: a policy framework for healthy ageing. Lancet. 2016 May 21;**387**(10033):2145-54. doi: 10.1016/S0140-6736-(15)00516-4. Epub 2015 Oct 29. PMID: 26520231; PMCID: PMC4848186.
2. Annuario Statistico Italiano. Rome: Istituto Nazionale di Statistica; 2022. Available from: https://www.istat.it/storage/ASI/2022/ASI_2022.pdf [Last accessed: 2025 Mar 6].

3. Available from: https://www.istat.it/it/files/2022/03/Il-Censimento-permanente-della-popolazione-in-Toscana_focus-2.pdf [Last accessed: 2025 Mar 6].
4. Fried LP, Ferrucci L, Darer J, Williamson JD, Anderson G. Untangling the Concepts of Disability, Frailty, and Comorbidity: Implications for Improved Targeting and Care. J Gerontol A Biol Sci Med Sci. 2004 Mar;**59**(3):M255-63. doi: 10.1093/gerona/59.3.m255. PMID: 15031310.
5. Paasche-Orlow MK, Wolf MS. The Causal Pathways Linking Health Literacy to Health Outcomes. Am J Health Behav. 2007 Sep-Oct;**31**(Suppl 1):S19-26. doi: 10.5555/ajhb.2007.31.supp.S19. PMID: 17931132.
6. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low Health Literacy and Health Outcomes: An Updated Systematic Review. Ann Intern Med. 2011 Jul 19;**155**(2):97-107. doi: 10.7326/0003-4819-155-2-201107190-00005. PMID: 21768583.
7. Sørensen K, Van Den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: A systematic review and integration of definitions and models. BMC Public Health. 2012 Jan 25;**12**(1):80. doi: 10.1186/1471-2458-12-80. PMID: 22276600; PMCID: PMC3292515.
8. Kickbusch I, Pelikan JM, Apfel F, Tsouros AD, World Health Organization. Health literacy: the solid facts. Copenhagen: World Health Organization Regional Office for Europe; 2013. 73 p.
9. Sørensen K, Pelikan JM, Röthlin F, Ganahl K, Slonska Z, Doyle G, et al. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). Eur J Public Health. 2015 Dec;**25**(6):1053-8. doi: 10.1093/eurpub/ckv043. Epub 2015 Apr 5. PMID: 25843827; PMCID: PMC4668324.
10. Chesser AK, Keene Woods N, Smothers K, Rogers N. Health Literacy and Older Adults: A Systematic Review. Gerontol Geriatr Med. 2016 Mar 15;**2**:233372141663049. doi: 10.1177/2333721416630492. PMID: 28138488; PMCID: PMC5119904.
11. McGilton KS, Vellani S, Yeung L, Chishtie J, Commisso E, Ploeg J, et al. Identifying and understanding the health and social care needs of older adults with multiple chronic conditions and their caregivers: a scoping review. BMC Geriatr. 2018 Oct 1;**18**(1):231. doi: 10.1186/s12877-018-0925-x. PMID: 30285641; PMCID: PMC6167839.
12. Bröder J, Chang P, Kickbusch I, Levin-Zamir D, McElhinney E, Nutbeam D, et al. IUHPE Position Statement on Health Literacy: a practical vision for a health literate world. Glob Health Promot. 2018 Dec 11;**25**(4):79-88. https://doi.org/10.1177/1757975918814421.
13. Tavousi M, Mohammadi S, Sadighi J, Zarei F, Kermani RM, Rostami R, et al. Measuring health literacy: A systematic review and bibliometric analysis of instruments from 1993 to 2021. Rios-González CM, curatore. PLoS One. 2022 Jul 15;**17**(7):e0271524. doi: 10.1371/journal.pone.0271524. PMID: 35839272; PMCID: PMC9286266.
14. Lorini C, Lastrucci V, Mantwill S, Vettori V, Bonaccorsi G; Florence Health Literacy Research Group. Measuring health literacy in Italy: a validation study of the HLS-EU-Q16 and of the HLS-EU-Q6 in Italian language, conducted in Florence and its surroundings. Ann Ist Super Sanita. 2019 Jan-Mar;**55**(1):10-8. doi: 10.4415/ANN_19_01_04. PMID: 30968831.
15. Epicentro. Available from: https://www.epicentro.iss.it/passi/en/english [Last accessed: 2025 Mar 6].
16. Baldissera S, Ferrante G, Quarchioni E, Minardi V, Possenti V, Carrozzi G, et al. Field substitution of nonresponders can maintain sample size and structure without altering survey estimates—the experience of the Italian behavioral risk factors surveillance system (PASSI). Ann Epidemiol. 2014 Apr;**24**(4):241-5. doi: 10.1016/j.annepidem.2013.12.003. Epub 2013 Dec 28. PMID: 24461932.
17. Unim B, De Vito C, Massimi A, D'Andrea E, Rosso A, Villari P, et al. The need to improve implementation and use of lifestyle surveillance systems for planning prevention activities: an analysis of the Italian Regions. Public Health. 2016 Jan;**130**:51-8. doi: 10.1016/j.puhe.2015.08.009. Epub 2015 Oct 1. PMID: 26427315.
18. Available from: https://www.oxfordbibliographies.com/display/document/obo-9780199756797/obo-9780199756797-0065.xml [Last accessed: 2025 Mar 6].
19. Zanobini P, Lorini C, Caini S, Lastrucci V, Masocco M, Minardi V, et al. Health Literacy, Socioeconomic Status and Vaccination Uptake: A Study on Influenza Vaccination in a Population-Based Sample. Int J Environ Public Health. 2022 Jun 6;**19**(11):6925. doi: 10.3390/ijerph19116925. PMID: 35682508; PMCID: PMC9180363.
20. Zanobini P, Lorini C, Lastrucci V, Minardi V, Possenti V, Masocco M, et al. Health Literacy, Socio-Economic Determinants, and Healthy Behaviours: Results from a Large Representative Sample of Tuscany Region, Italy. Int J Environ Res Public Health. 2021 Nov 26;**18**(23):12432. doi: 10.3390/ijerph182312432. PMID: 34886157; PMCID: PMC8656600.
21. Pelikan JM, Ganahl K. Measuring Health Literacy in General Populations: Primary Findings from the HLS-EU Consortium's Health Literacy Assessment Effort. Stud Health Technol Inform. 2017;**240**:34-59. PMID: 28972508.
22. Pander Maat H, Essink-Bot ML, Leenaars KE, Fransen MP. A short assessment of health literacy (SAHL) in the Netherlands. BMC Public Health. 2014 Sep 23;**14**(1):990. doi: 10.1186/1471-2458-14-990. PMID: 25246170; PMCID: PMC4190424.
23. Pelikan JM, Röthlin F, Ganahl K. Measuring comprehensive health literacy in general populations: validation of instrument, indices and scales of the HLS-EU study. 6th Annual Health Literacy Research Conference. Bethesda, Maryland: November 3-4, 2014. Available from: www. bumc.bu.edu/healthliteracyconference/files/2014/06/ Pelikan-et-al-HARC-2014-fin.pdf [Last accessed: 2025 Mar 6].
24. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Structural Equation Modeling: A Multidisciplinary Journal. 1999 Jan;**6**(1):1-55. https://doi.org/10.1080/10705519909540118.

25. Paasche-Orlow MK, Parker RM, Gazmararian JA, Nielsen-Bohlman LT, Rudd RR. The prevalence of limited health literacy. J Gen Intern Med. 2005 Feb;**20**(2):175-84. doi: 10.1111/j.1525-1497.2005.40245.x. PMID: 15836552; PMCID: PMC1490053.
26. Rikard RV, Thompson MS, McKinney J, Beauchamp A. Examining health literacy disparities in the United States: a third look at the National Assessment of Adult Literacy (NAAL). BMC Public Health. September 2016 Sep 13;**16**(1):975. doi: 10.1186/s12889-016-3621-9. PMID: 27624540; PMCID: PMC5022195.
27. Mantwill S, Monestel-Umaña S, Schulz PJ. The Relationship between Health Literacy and Health Disparities: A Systematic Review. PLoS One. 2015 Dec 23;**10**(12):e0145455. doi: 10.1371/journal.pone.0145455. PMID: 26698310; PMCID: PMC4689381.
28. Nguyen TH, Paasche-Orlow MK, McCormack LA. The State of the Science of Health Literacy Measurement. Stud Health Technol Inform. 2017;**240**:17-33. PMID: 28972507; PMCID: PMC6082165.
29. The HLS19 Consortium of the WHO Action Network M-POHL. International Report on the Methodology, Results, and Recommendations of the European Health Literacy Population Survey 2019-2021 (HLS19) of M-POHL. Vienna, December 2021.
30. Coman MA, Forray AI, Van Den Broucke S, Chereches RM. Measuring Health Literacy in Romania: Validation of the HLS-EU-Q16 Survey Questionnaire. Int J Public Health. 2022 Feb 4;**67**:1604272. doi: 10.3389/ijph.2022.1604272. PMID: 35185446; PMCID: PMC8855985.
31. Carozza P. Contrastare lo stigma della malattia mentale: obiettivo dei servizi di salute mentale di comunità. Journal of Health Care Education in Practice. 2021 Nov;**3**(2):15-26. doi: 10.14658/PUPJ-jhcep-2021-2-3.
32. Gele AA, Pettersen KS, Torheim LE, Kumar B. Health literacy: the missing link in improving the health of Somali immigrant women in Oslo. BMC Public Health. 2016 Nov 3;**16**(1):1134. doi: 10.1186/s12889-016-3790-6. PMID: 27809815; PMCID: PMC5093985.
33. Gustafsdottir SS, Sigurdardottir AK, Arnadottir SA, Heimisson GT, Mårtensson L. Translation and cross-cultural adaptation of the European Health Literacy Survey Questionnaire, HLS-EU-Q16: the Icelandic version. BMC Public Health. 2020 Jan 14;**20**(1):61. doi: 10.1186/s12889-020-8162-6. PMID: 31937293; PMCID: PMC6961374.
34. Rouquette A, Nadot T, Labitrie P, Van den Broucke S, Mancini J, Rigal L, et al. Validity and measurement invariance across sex, age, and education level of the French short versions of the European Health Literacy Survey Questionnaire. PLoS One. 2018 Dec 6;**13**(12):e0208091. doi: 10.1371/journal.pone.0208091. PMID: 30521552; PMCID: PMC6283623.
35. Dsouza JP, Van Den Broucke S, Pattanshetty S. Validity and Reliability of the Indian Version of the HLS-EU-Q16 Questionnaire. Int J Environ Rea Public Health. 2021 Jan 9;**18**(2):495. doi: 10.3390/ijerph18020495. PMID: 33435372; PMCID: PMC7827499.
36. Levin-Zamir D, Baron-Epel OB, Cohen V, Elhayany A. The Association of Health Literacy with Health Behavior, Socioeconomic Indicators, and Self-Assessed Health From a National Adult Survey in Israel. Journal of Health Communication. August 2016;21(Suppl 2):61-8. doi: 10.1080/10810730.2016.1207115. Epub 2016 Sep 26. PMID: 27669363.
37. Tiller D, Herzog B, Kluttig A, Haerting J. Health literacy in an urban elderly East-German population – results from the population-based CARLA study. BMC Public Health. 2015 Sep 10;**15**(1):883. doi: 10.1186/s12889-015-2210-7. PMID: 26357978; PMCID: PMC4566302.
38. Bergman L, Nilsson U, Dahlberg K, Jaensson M, Wångdahl J. Validity and reliability of the swedish versions of the HLS-EU-Q16 and HLS-EU-Q6 questionnaires. BMC Public Health. 2023 Apr 20;**23**(1):724. doi: 10.1186/s12889-023-15519-9. PMID: 37081538; PMCID: PMC10117247.
39. Duplaga M. Determinants and Consequences of Limited Health Literacy in Polish Society. Int J Environ Res Public Heath. 2020 Jan 19;**17**(2):642. doi: 10.3390/ijerph17020642. PMID: 31963834; PMCID: PMC7014389.
40. Svendsen MT, Bak CK, Sørensen K, Pelikan J, Riddersholm SJ, Skals RK, et al. Associations of health literacy with socioeconomic position, health risk behavior, and health status: a large national population-based survey among Danish adults. BMC Public Health. 2020 Apr 28;**20**(1):565. doi: 10.1186/s12889-020-08498-8. PMID: 32345275; PMCID: PMC7187482.
41. Wu JR, Moser DK, DeWalt DA, Rayens MK, Dracup K. Health Literacy Mediates the Relationship Between Age and Health Outcomes in Patients With Heart Failure. Circ Heart Fail. 2016 Jan;**9**(1):e002250. doi: 10.1161/CIRCHEARTFAILURE.115.002250. PMID: 26721913; PMCID: PMC4698978.
42. Kaphingst KA, Goodman MS, MacMillan WD, Carpenter CR, Griffey RT. Effect of cognitive dysfunction on the relationship between age and health literacy. Patient Educ Couns. 2014 May;**95**(2):218-25. doi: 10.1016/j.pec.2014.02.005. Epub 2014 Feb 22. PMID: 24629836; PMCID: PMC4172373.
43. Vogt D, Schaeffer D, Messer M, Berens EM, Hurrelmann K. Health literacy in old age: results of a German cross-sectional study. Health Promot Int. 2018 Oct 1;**33**(5):739-47. doi: 10.1093/heapro/dax012. PMID: 28369348.
44. Cutilli CC. Health Literacy in Geriatric Patients: An Integrative Review of the Literature. Orthop Nurs. 2007 Jan-Feb;**26**(1):43-48. doi: 10.1097/00006416-200701000-00014. PMID: 17273109.
45. Nutbeam D, Lloyd JE. Understanding and Responding to Health Literacy as a Social Determinant of Health. Annu Rev Public Health. 2021 Apr 1;**42**(1):159-73. doi: 10.1146/annurev-publhealth-090419-102529. Epub 2021 Oct 9. PMID: 33035427.
46. Estrela M, Semedo G, Roque F, Ferreira PL, Herdeiro MT. Sociodemographic determinants of digital health literacy: A systematic review and meta-analysis. Internat J Med Inform. 2023 Sep;**177**:105124. doi: 10.1016/j.ijmedinf.2023.105124.

Epub 2023 Jun 10. PMID: 37329766.
47. Lorini C, Lastrucci V, Paolini D, Bonaccorsi G. Measuring health literacy combining performance-based and self-assessed measures: the roles of age, educational level and financial resources in predicting health literacy skills. A cross-sectional study conducted in Florence (Italy). BMJ Open. October 2020 Oct 5;**10**(10):e035987. 2020 Oct 5;10(10):e035987. doi: 10.1136/bmjopen-2019-035987. PMID: 33020080; PMCID: PMC7537461.
48. Jordan S, Hoebel J. Gesundheitskompetenz von Erwachsenen in Deutschland: Ergebnisse der Studie "Gesundheit in Deutschland aktuell" (GEDA). [Health literacy of adults in Germany: Findings from the German Health Update (GEDA) study]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2015 Sep;**58**(9):942-50. German. doi: 10.1007/s00103-015-2200-z. PMID: 26227894.
49. Schaeffer D, Berens EM, Vogt D. Health Literacy in the German Population. Dtsch Arztebl Int. 2017 Jan 27;**114**(4):53-60. doi: 10.3238/arztebl.2017.0053. PMID: 28211318; PMCID: PMC5319379.
50. Warr P. Work, Well-Being, and Mental Health. In: Barling J, Kelloway EK, Frone MR, Eds. Handbook of Work Stress [Internet]. Thousand Oaks, CA (US): SAGE Publications, Inc.; 2005 [cited 20 September 2024]. p. 547-74. Available from: https://sk.sagepub.com/reference/hdbk_workstress/n23.xml [Last accessed: 2025 Mar 6].
51. Calvo E, Haverstick K, Sass SA. Gradual Retirement, Sense of Control, and Retirees' Happiness. Res Aging. 2009 Jan 1;**31**(1):112-35. https://doi.org/10.1177/0164027508324704.
52. Epicentro. Available from: https://www.epicentro.iss.it/en/passi-argento/ [Last accessed: 2025 Mar 6].

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Knowledge, attitudes and practices about Cannabis light among a sample of Italian undergraduates

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Keywords: Cannabis light; tetrahydrocannabinol; cannabidiol; drug; undergraduates
Parole chiave: Cannabis light; tetraidrocannabinolo; cannabinolo; droga; studenti universitari

Abstract

Background. *Over the past few years, the market for "cannabis light", substance with a tetrahydrocannabinol content of less than 0.6% (according to Italian law), has become established. The aim of the present study was to evaluate knowledge, attitudes and practices about cannabis light products among a sample of Italian undergraduates.*
Methods. *This cross-sectional study was conducted in the academic year 2023/2024. Participants completed an anonymous questionnaire regarding socio-demographic data, knowledge about cannabis light products and their effects, attitudes and practices related to these products. Responses on knowledge were aggregated into a dichotomous variable ("good knowledge" and "poor knowledge"). A multivariate analysis was performed on the knowledge variable using age, gender, type of secondary school attended, tobacco use and having used cannabis light-containing products as independent variables.*
Results. *Only 24.6% of the sample stated that they had used a product containing cannabis light at least once and 70.1% showed poor knowledge about such products. Students from technical or vocational secondary schools were significantly less likely to have good knowledge (OR=0.4; 95%CI=0.19-0.88). In contrast, those who had used these products at least once were more likely to have good knowledge (OR=4.8; 95%CI=2.84-8.25).*
Conclusions. *Despite the increasing popularity of cannabis light products, the level of knowledge among university students remains low. Therefore, interventions are needed to fill knowledge gaps about these products and to guarantee their informed use.*

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Introduction

Cannabis is the most widely used drug globally (1), approximately 20% of the youth population in Europe aged 15 to 24 reported to have used the substance at least once (2). The effects are due to its cannabinoid components, in particular tetrahydrocannabinol (THC) and cannabidiol (CBD) (3). THC is the only psychoactive compound in cannabis, while CBD is the most famous non-psychoactive component (4), and it is considered a natural remedy for health conditions (5). A number of several studies have demonstrated the potential benefits of CBD as a treatment for the management of pain, anxiety, insomnia, depression, schizophrenia and opioid abuse (5). In 2018, the US Food and Drug Administration (FDA) approved a CBD-based medication for treating specific forms of epilepsy (6) and, in 2019, the World Health Organization (WHO) recognized cannabis as a therapeutic substance (7). In the United States alone, it has been estimated that 3.5 million people use cannabis for medical purposes (8).

Recently, the market has seen the rise of cannabis "light", characterized by high CBD and low THC content. This form of cannabis is available in various products, including smokables, inhalants, oils, lotions, and edibles. It has been demonstrated to have a high safety profile, minimizing the adverse effects associated with THC (9).

The Italian Government approved in 2016 the Law 242/16 to facilitate the cultivation of hemp and its sale, considered legal if the THC content does not exceed 0.6% (10). It applies to hemp crops of the allowed varieties listed in the Common Catalogue of Varieties of Agricultural Species, pursuant to Article 17 of the European Union Council Directive 2002/53/EC of 13 June 2002 (11). This law has led to the birth of a flourishing market that counts over 2,000 points of sale throughout the country and over 1,500 agricultural holdings, for a total of 10,000 employees in the sector (12). To these numbers should also be added the online marketing of these products.

Despite the widespread consumption of these products, there is limited scientific evidence on how CBD is acquired and used, and on the possible adverse effects resulting from its intake. In recent years, a growing phenomenon of "self-medication" has been observed using these products to treat insomnia, anxiety, and chronic pain; in some cases, CBD-containing products are taken together with alcohol, drugs and medications, increasing their effects (also adverse effects) (13). Moreover, both regular and occasional users are often unaware of the composition of the products they use, of the possible side and/or synergistic effects (due to the simultaneous use of other substances) and of the possible risks associated with misuse (14). Such occurrences inevitably result in public health issues that cannot be overlooked.

Given the ever-increasing market concerning cannabis light products and the continuous introduction of new products of this type, it is necessary to produce objective evidence useful for public health professionals. This would be essential to open a dialogue with consumers and the general population, with the purpose of increasing knowledge about these products and awareness of their use, to reduce the possibility of misbehavior and misuse.

The aim of the present study was to evaluate knowledge, attitudes and practices about cannabis light products among a sample of Italian university students.

Methods

1. Study design and participants

This was a cross-sectional study carried out on 500 students attending the Sapienza University of Rome. The research project was illustrated to all the students in the classrooms, after clarifying the purposes and the reasons of the survey. Knowledge, attitudes and practices of participants were assessed through a self-administered, anonymous questionnaire elaborated "ad hoc" and validated before the beginning of the study. The questionnaire was administered to the students of different degree courses on different days in the academic year 2023-2024. The protocol of the study was approved (Protocol n. 0256/2022) by the Ethics Committee of the Teaching Hospital Policlinico Umberto I of Rome, house of the Clinical Departments of the first and second Medical Schools of the Sapienza University.

2. Questionnaire

The questionnaire consisted of three sections: the first one collects the sociodemographic information (gender, age, nationality, secondary school attended, degree course attended, first year of enrollment, participants' residential status, parents' educational level); the second evaluates the knowledge about cannabis light products and the possible therapeutic and adverse effects; the last one assesses information about those who reported consuming these products. All the answers were coded and added in a database, specifically elaborated for statistical purposes.

3. Covariates and statistical analysis

The database management and statistical analyses were performed using STATA, version 18 (StataCorp LLC, College Station, Texas USA).

A descriptive analysis was performed on sociodemographic characteristics and answers of participants. Continuous variables were expressed as mean values ± standard deviation (SD) while categorical variables were reported as number and percentage values of respondents. Univariate analysis was performed to assess possible associations between knowledge and categorical variables using the chi squared test (with Yates's correction) and with continuous variables using Mann-Whitney U Test. Finally, multivariate logistic regression was used to assess the possible association between knowledge and the variables which resulted significantly associated to knowledge in the univariate analysis.

To perform univariate and multivariate analyses, the variables were codified as follows: gender was expressed as female = 0 and male = 1 and the nationality as Italian = 0 and other = 1. Besides, the secondary school attended was coded as "Lyceum education" = 0 and Others = 1, according to the name of programme in national language described by the Organisation for Economic Co-operation and Development (OECD) (15).

Participants' residential status was coded as follows: "Resident" = 0 and "Commuting or non-resident student" = 1, while parents' educational level was codified as 0 = "Up to secondary school" and 1 = "Degree or postgraduate education". Last year's use of tobacco's products was coded as follows: "No" = 0 and "Yes" = 1.

The variable "Cannabis light knowledge" was constructed from the scores of five questions ("What is cannabis light?", "What types of products containing cannabis light can be purchased?", "Can products containing cannabis light give adverse effects?", "Can cannabis light be used for medicinal purposes?", "Amount of THC allowed in cannabis light according to the laws of Italy"). The question "What is light cannabis?" was coded into "Don't know" = 0, "CBD-rich substance" = 1, "THC-rich substance" = 2 and then aggregated as dichotomous ("THC-rich substance/Don't know" = 0 and "CBD-rich substance" = 1). The question "Can cannabis light products give undesirable effects?" consisted of 7 products, each affirmative answer was given a value of 1 and each uncertain or incorrect answer a value of 0, creating a numeric variable from 0 to 7. This was dichotomized according to the median value. The question "Amount of THC permitted in light cannabis according to the Italian state" was coded as follows: in "THC > 3.0%/ Don't know" = 0 and "THC < 0.6%" = 1. The two remaining questions were coded as follows "No/Don't know" = 0 and "Yes" = 1.

The variable "Cannabis Light Knowledge" was dichotomized using median value as follows: "Poor Knowledge" = 0 and "Good Knowledge" = 1.

In the multivariate analysis, odds ratio (OR) and 95% confidence intervals (CIs) were calculated. The significance level was assumed as $p < 0.05$.

Results

In total, 500 students responded to the questionnaire and 462 observations were included in the univariate analysis, and 448 used in the multivariate analysis. Socio-demographic characteristics of the sample were summarized in Table 1.

The mean age of participants was 25.7 ± 6.9 years. The sample included mainly females (67.6%) and most participants were Italians (94.2%). Almost 87% of students had a Lyceum education, the remaining 13% came from technical institutes. The distribution by study area of the degree course attended showed a predominance of students coming from scientific disciplines (96.4%) compared to those from the humanities (3.6%).

Almost two-thirds of the sample (61.2%) were non-residents or commuters, while 38.8% resided in the same city of the university attended. Parental educational levels varied as follows: 56.9% of mothers and 58.3% of fathers studied until to secondary school, while 43.1% of mothers and 41.7% of fathers had at least a university degree. A total of 45.8% of the sample reported using tobacco in the past year.

Table 2 presents data related to the knowledge on products containing cannabis light. Almost half of the sample did not know the definition of light cannabis or provided an incorrect definition and 54% of the participants incorrectly stated that the legally permitted THC content in Italy is above 3% or they were unaware of the correct limit. Considering these last two questions and those related to cannabis light products, the median number of correct answers was 3 in a range from 0 to 7, and 70% of the students demonstrated poor knowledge.

Participants' attitude and practices related to cannabis light was presented in Table 3. Less than 25% of students reported having tried light cannabis at least once and the age of first use was for 63% of them

Table 1 - Main socio-demographic characteristics of the sample

Variable	Value
Age (years)	
Mean Value ± SD	25.68 ± 6.89
Median Value (interquartile range)	23 (7)
Range	18-68
Age n (%)	
<23 years	253 (50.6)
≥23 years	247 (49.4)
Gender n (%)	
Female	338 (67.60)
Male	162 (32.40)
Nationality n (%)*	
Italian	470 (94.19)
Other	29 (5.81)
Secondary school attended n (%)*	
Lyceum	430 (86.87)
Other	65 (13.13)
Study area of the degree course attended n (%)*	
Scientific Studies	476 (96.36)
Humanities Studies	18 (3.64)
Residential status n (%)*	
Off-site/Commuter	304 (61.17)
Resident	193 (38.83)
Mother's educational level n (%)*	
Until to secondary school	282 (56.85)
Degree or postgraduate education	214 (43.15)
Father's educational level n (%)*	
Until to secondary school	288 (58.30)
Degree or postgraduate education	206 (41.70)
Use of tobacco products last year n (%)*	
Yes	223 (45.79)
No	264 (54.21)

* This variable has some missing answers

between of 18 and 25. The cannabis light consumption resulted not so high, with a 6% of participants using these products several times a week.

A univariate analysis was conducted to assess the possible association between the variables examined and the knowledge of cannabis light (Table 4): type of secondary school attended, mother's educational level, use of tobacco products and use of cannabis light products were significantly related with knowledge.

Finally, logistic regression models were built to identify variables independently associated with knowledge (Table 5). Mother's educational level was removed from the final model according to LR test. Previous use of cannabis-containing products was the strongest predictor of good knowledge of cannabis light (OR = 4.85, CI 95% = 2.85 - 8.25, p < 0.001). Students who attended technical institutes had significantly lower odds of having good knowledge of cannabis light compared to those who had attended an academic high school (OR = 0.41, CI 95% = 0.19 - 0.89, p = 0.02).

Discussion

The first relevant result is related to the knowledge of the sample about the products under study: a significant portion of participants lack adequate awareness of cannabis light and its health-related implications. This result is in line with those of a previous study on products that contain CBD performed on a sample of German individuals. In particular, the German study found that more than half of respondents have not heard of CBD and most of them rated the health risks as low or very low (16). In addition, students who had previously used cannabis light products demonstrated significantly better knowledge of cannabis light. This trend is also confirmed by a study conducted in France (17). In this case, users were more aware of the health safety of cannabis light products, their composition and therapeutic effects than non-users. The latter, on the other hand, were more aware of the possibility of physical dependence and the toxic effects that these products may have. Indeed, products containing CBD can cause gastrointestinal symptoms, mild central nervous system depression, tachycardia, dizziness/vertigo, vomiting, nausea and agitation; besides, several toxics effects on liver, endocrine system and reproductive function are reported and should be studied in depth (18). These effects can be due to the direct pharmacological action of CBD or to the degradation of CBD to Δ 9-THC in the stomach after oral consumption or to the Δ 9-THC contained in the products as by-product due to contamination or to co-extraction and enrichment. Thus, given the growing market for some of these products, it is essential to challenge the operators' responsibility for the safety of the product and for regulatory compliance and to improve strong regulatory framework in this field (18). Recently, the new Decree-Law on Citizen Security approved by the Italian government on April 4, 2025 imposes severe restrictions, prohibiting the importation, production, processing, distribution, marketing and delivery of Cannabis sativa L.

Table 2 - Participants' knowledge about cannabis light

What is cannabis light n (%)*		Substance rich in CBD	253 (51.42)
		Substance rich in THC/I don't know	239 (48.58)
Purchasable cannabis light containing products	Smoking products n (%)*	Yes	321 (67.15)
		No/I don't know	157 (32.85)
	Creams and unguents n (%)*	Yes	256 (54.01)
		No/I don't know	218 (45.99)
	Oils and essences n (%)*	Yes	285 (60.13)
		No/I don't know	189 (39.87)
	Foods n (%)*	Yes	242 (51.16)
		No/I don't know	231 (48.84)
	Drinks n (%)*	Yes	187 (39.79)
		No/I don't know	283 (60.21)
	Cosmetics n (%)*	Yes	178 (37.87)
		No/I don't know	292 (62.13)
Cannabis light products undesirable effects n (%)*		Yes	243 (50.31)
		No/I don't know	240 (49.69)
Cannabis light products therapeutic use n (%)*		Yes	310 (64.05)
		No/I don't know	174 (35.95)
Cannabis light products THC content in Italy n (%)*		THC < 0.6%	223 (46.17)
		THC > 3.0%/I don't know	260 (53.83)
Cannabis light products possible adverse effects	Dry mouth n (%)*	Yes	176 (51.31)
		No	167 (48.69)
	Stun n (%)*	Yes	202 (59.59)
		No	137 (40.41)
	Appetite alteration n (%)*	Yes	205 (59.77)
		No	138 (40.23)
	Interactions n (%)*	Yes	192 (55.81)
		No	152 (44.19)
	Liver effects n (%)*	Yes	83 (24.41)
		No	257 (75.59)
	Cardiovascular effects n (%)*	Yes	160 (46.78)
		No	182 (53.22)
Cannabis light products therapeutic use	Gastrointestinal effects n (%)*	Yes	124 (36.47)
		No	216 (63.53)
	Respiratory effects n (%)*	Yes	167 (48.69)
		No	176 (51.31)
	Fatigue n (%)*	Yes	132 (38.71)
		No	209 (61.29)
	Chronic pain n (%)*	Yes	286 (74.67)
		No	97 (25.33)
	Head trauma n (%)*	Yes	69 (18.16)
		No	311 (81.84)
	Migraine n (%)*	Yes	217 (56.81)
		No	165 (43.19)
	Epilepsy n (%)*	Yes	129 (34.49)
		No	245 (65.51)
	Insomnia n (%)*	Yes	246 (64.91)
		No	133 (35.09)
	Anxiety/Stress n (%)*	Yes	274 (71.73)
		No	108 (28.27)
	Parkinson n (%)*	Yes	177 (46.58)
		No	203 (53.42)
	Alzheimer n (%)*	Yes	87 (22.96)
		No	292 (77.04)
	Mood Alteration n (%)*	Yes	137 (35.96)
		No	244 (64.04)
Cannabis light knowledge n (%)*		Poor Knowledge	324 (70.13)
		Good Knowledge	138 (29.87)

*This variable has some missing answers

Table 3 - Participants' attitude and practices related to cannabis light

Ever used cannabis light products n (%)*	Yes	119 (24.64)
	No	364 (75.36)
Age of cannabis light first use n (%)§	< 17 years	26 (21.85)
	18-25 years	75 (63.03)
	26-30 years	17 (14.29)
	>31 years	1 (0.84)
Cannabis light consumption frequency n (%)*,§	< once a week	36 (31.03)
	2-4 times a week	5 (4.31)
	>5 times a week	3 (2.59)
	I only tried once	72 (62.07)
CBD knowledge n (%)*,§	Yes	34 (29.57)
	No	81 (70.43)
Combined use n (%)*,§	Yes	20 (17.70)
	No	93 (82.30)

*This variable has some missing answers
§This question was administered just to participants who reported having consumed cannabis light products at least once (n = 119)

Table 4. Association between the knowledge about cannabis light and socio-demographic characteristics or attitude vs smoking tobacco or using cannabis light products

Variable*		Bad Knowledge	Good Knowledge	p-value
Age (years)		25.96 ± 7.52	25.31 ± 4.63	0.25
Gender	Females	224 (69.14)	83 (60.14)	0.06
	Males	100 (30.86)	55 (39.86)	
Nationality	Italian	302 (93.21)	133 (96.38)	0.18
	Other	22 (6.79)	5 (3.62)	
School level	Lyceum	272 (84.21)	126 (92.65)	**0.02**
	Other	51 (15.79)	10 (7.35)	
Study area	Scientific Studies	309 (96.56)	132 (96.35)	0.91
	Humanities Studies	11 (3.44)	5 (3.65)	
Residence condition	Resident	114 (35.19)	56 (40.58)	0.27
	Off-site/Commuter	210 (64.81)	82 (59.42)	
Mother's educational level	Until to secondary school	201 (62.04)	68 (49.28)	**0.01**
	Degree or postgraduate education	123 (37.96)	70 (50.72)	
Father's educational level	Until to secondary school	195 (60.56)	79 (57.25)	0.51
	Degree or postgraduate education	127 (39.44)	59 (42.75)	
Use of tobacco products last year	Yes	129 (40.31)	81 (60.90)	**<0.01**
	No	191 (59.69)	52 (39.10)	
Ever used cannabis light products	Yes	47 (14.55)	67 (48.55)	**<0.01**
	No	276 (85.45)	71 (51.45)	

*All variables have some missing answers

Table 5 - Logistic Regression: variables independently associated with Cannabis Light knowledge

Variable		Odds Ratio (ORs)	Confidence Intervals (95% IC)	p-value
Age		0.99	0.96 - 1.03	0.76
Gender	Female (reference)	1.00		0.17
	Male	1.39	0.87 - 2.21	
Secondary school attended	Lyceum (reference)	1.00		**0.02**
	Other	0.41	0.19 - 0.88	
Use of tobacco	No (reference)	1.00		0.40
	Yes	1.24	0.75 - 2.06	
Ever used products	No (reference)	1.00		**<0.001**
	Yes	4.85	2.85 - 8.25	

inflorescences, including CBD flowers, CBD resins and CBD oils, regardless of their compliance with legal THC limits. However, this Decree is not in line with the European regulatory framework and, thus, it is not certain that it will be able to come into force (In Italy, Decree-Laws, issued by the Government and immediately valid for 2 months, must be re-approved – as such or modified – by the Parliament within the period of validity, under penalty of lapse). Besides, even if it will be approved, the Italian citizen will be free to buy products containing CBD in other Europe countries. Consequently, although the laws protecting human health could be considered an essential prevention tool, integrated strategies are necessary in order to successfully contrast the possible health risks associated with products containing CBD.

Partial knowledge may indeed influence whether or not to use such products. In addition, this could suggest that firsthand experience drives individuals to seek more information about the substances they consume. Conversely, those with no prior usage may rely on misinformation or lack of awareness altogether, as evidenced by the 54% of participants who incorrectly identified the legal THC limit or were unaware of it.

The type of secondary school attended by the participants could also play a role in reaching correct knowledge or not. Indeed, students having a Lyceum education exhibited better awareness compared to their peers from Technical Institutes. This finding is innovative as, in our knowledge, no articles investigating this association have been found in the literature. This may reflect differences in curriculum exposure to scientific knowledge or critical thinking skills, underscoring the need for educational interventions across school types.

Additionally, research has pointed out that university students tend to have limited knowledge about health-related topics, even when these subjects are highly relevant to their lifestyle choices and personal experiences. This aligns with findings from previous studies on body art awareness, which indicate that, while university students may be aware of general health risks, they often lack specific knowledge about complications and contraindications (19). In the context of CBD, this knowledge gap suggests a broader issue in health literacy among university populations, where increasing access to products does not necessarily correlate with informed use. Knowledge of the topic also influences perceptions of the risks and benefits of cannabis, as shown by a study on Austrian medical students. In this case, the male population was more supportive of the legalisation and prescription of cannabis for medical purposes, in contrast to the female population, that focused more on the adverse effects and health risks (20). The increased acceptance by medical students of cannabis for medicinal purposes suggests that the medical community should prioritise the development of specific educational programmes. In this way, such treatments would have a greater chance of success as safe and viable therapies (21).

Another relevant result emerged from the present study is that approximately a quarter of the sample studied are cannabis light products' users. Such a finding is not comparable with other studies because research reporting data on the use of products containing cannabis did not report the percentage of THC in the products. However, one study outlined that prevalence rates of cannabis use may be higher among university students than in the general population (22). In fact, up to 25% of young people start using cannabis after admission to university and cannabis use in the last 12 months among them is around 20-30% (23). The latter figure is in line with our percentage, which is 23.8%.

Moreover, the age of first use aligns with university years, suggesting that this population group is particularly vulnerable to both experimenting with, and misunderstanding, the properties and effects of cannabis light products. One of the key findings is that nearly two-thirds of our students tried cannabis light at the age between 18 and 25 years old. This period coincides with increased academic pressures, social transitions, and personal stressors commonly experienced during university life. This data is confirmed by a German study, which finds that the use of cannabis is more frequent in the age group under 30 years (16). This result is further strengthened by data from the European Drug Observatory, which states that, in Europe, about 10% of those 15–24-years old recently used cannabis (24). Previous research has indicated that young adults often resort to substances like cannabis to manage stress and anxiety, given the widely publicized calming effects of CBD (25,26). However, the misuse of such products for self-medication could mask underlying mental health issues and lead to unintentional side effects, especially when combined with other substances like alcohol or tobacco (27). This is a further essential point which pushes to develop new strategies for the prevention of smoking and alcohol abuse, for which the adverse effects are well known.

The potential long-term effects and dependency risks remain an area of concern: recent findings

indicate that CBD use can influence emotional regulation and cognitive function, potentially leading to altered stress responses in young adults (28).

Conclusions

Given the burgeoning market for products containing cannabis light and the increasing trend of self-medication among young adults, it is important for public health professionals to design targeted educational campaigns specifically devoted to these products. In particular, initiatives should aim to improve awareness about the legal, health, and safety aspects of cannabis light use, particularly focusing on the university population that appears most susceptible to its experimentation and misuse.

Riassunto

Conoscenze, attitudini e pratiche sulla Cannabis light in un campione di studenti universitari Italiani

Premessa. Negli ultimi anni si è affermato il mercato della "cannabis light", sostanza con contenuto di tetraidrocannabinolo inferiore a 0,6% (secondo la legge italiana). Lo scopo dello studio era valutare le conoscenze, le attitudini e le pratiche circa i prodotti contenenti cannabis light di un gruppo di studenti universitari Italiani.

Metodi. Questo studio trasversale è stato condotto nell'anno accademico 2023/2024. I partecipanti hanno completato un questionario anonimo riguardante dati socio-demografici, conoscenza sui prodotti contenenti cannabis light e loro effetti, e consumo degli stessi. Le risposte sulla conoscenza sono state aggregate in una variabile dicotomica ("buona conoscenza" e "scarsa conoscenza"). Sulla variabile "conoscenza" è stata effettuata un'analisi multivariata utilizzando come variabili indipendenti l'età, il genere, il tipo di scuola secondaria frequentata, il consumo di tabacco e l'aver utilizzato prodotti contenenti cannabis light.

Risultati. Solo il 24,6% del campione ha dichiarato di aver utilizzato almeno una volta un prodotto contenente cannabis light e il 70,1% ha dimostrato una scarsa conoscenza riguardo tali prodotti. Gli studenti provenienti da scuole secondarie tecniche o professionali hanno mostrato una probabilità significativamente inferiore di avere una buona conoscenza (OR=0,4; IC95%=0,19-0,88). Al contrario, coloro che hanno utilizzato almeno una volta questi prodotti presentavano una maggiore probabilità di avere una buona conoscenza (OR=4,8; IC 95%=2,84-8,25).

Conclusioni. Nonostante la crescente popolarità dei prodotti contenenti cannabis light, il livello di conoscenza tra gli studenti universitari rimane basso. Pertanto, sono necessari interventi per colmare le lacune conoscitive su questi prodotti e per garantire un uso consapevole.

References

1. Hindley G, Beck K, Borgan F, Ginestet CE, McCutcheon R, Kleinloog D, et al. Psychiatric symptoms caused by cannabis constituents: a systematic review and meta-analysis. Lancet Psychiatry. 2020 Apr;**7**(4):344-353. doi: 10.1016/S2215-0366(20)30074-2. PMID: 32197092.
2. European Monitoring Centre for Drugs and Drug Addiction. European Drug Report 2019: Trends and Developments. European Drug Report. 2019 Jun 6; Available from: https://www.emcdda.europa.eu/publications/edr/trends-developments/2019_en [Last accessed: 2025 Feb 20].
3. Chayasirisobhon S. Mechanisms of Action and Pharmacokinetics of Cannabis. Perm J. 2020 Dec;**25**:1-3. doi: 10.7812/TPP/19.200. PMID: 33635755.
4. Lucas CJ, Galettis P, Schneider J. The pharmacokinetics and the pharmacodynamics of cannabinoids. Br J Clin Pharmacol. 2018 Nov;**84**(11):2477-2482. doi: 10.1111/bcp.13710. PMID: 30001569.
5. Huestis MA, Solimini R, Pichini S, Pacifici R, Carlier J, Busardò FP. Cannabidiol Adverse Effects and Toxicity. Curr Neuropharmacol. 2019;**17**(10):974-989. doi: 10.2174/1570159X17666190603171901. PMID: 31161980.
6. FDA. FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy. FDA News Release. 2018 Jun 25; Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derivedmarijuana-treat-rare-severe-forms [Last accessed: 2025 Feb 20].
7. Mayor S. WHO proposes rescheduling cannabis to allow medical applications. BMJ. 2019 Feb 5;**364**:l574. doi: 10.1136/bmj.l574. PMID: 30723076.
8. The Editors of ProCon. Medical Marijuana. Should Medical Marijuana Be Legal? Encyclopedia Britannica. 2025 Feb 10; Available from: https://www.britannica.com/procon/medical-marijuana-debate [Last accessed: 2025 Feb 20].
9. Mead A. The legal status of cannabis (marijuana) and cannabidiol (CBD) under U.S. law. Epilepsy Behav. 2017 May;**70**(Pt B):288-291. doi: 10.1016/j.yebeh.2016.11.021. PMID: 28169144.
10. Legge n. 242, 2016 Dec 2. Disposizioni per la promozione della coltivazione e della filiera agroindustriale della canapa. Gazzetta Ufficiale della Repubblica Italiana. 2016 Dec 30; Available from: https://www.gazzettaufficiale.it/eli/id/2016/12/30/16G00258/sg [Last accessed: 2025 Feb 20].
11. EUR-Lex. Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species. Official Journal L 193. 2002 Jul 20; Available from: EUR-Lex - 32002L0053 - EN - EUR-Lex (europa.eu) [Last accessed: 2025 Feb 20].
12. Romeo A. Per la cannabis in Italia un giro d'affari potenziale di 30 miliardi. Il Sole 24 ORE. 2019 Dec 13; Available from: https://www.ilsole24ore.com/art/per-cannabis-italia-giro-d-affari-potenziale-30-miliardi-ACSDpK5 [Last accessed: 2025 Feb 20].

13. Wheeler M, Merten JW, Gordon BT, Hamadi H. CBD (Cannabidiol) Product Attitudes, Knowledge, and Use Among Young Adults. Subst Use Misuse. 2020 Feb 24;**55**(7):1138-1145. doi: 10.1080/10826084.2020.1729201. PMID: 32093530.
14. Corroon J, Phillips JA. A Cross-Sectional Study of Cannabidiol Users. Cannabis Cannabinoid Res. 2018 Jul 1;**3**(1):152-161. doi: 10.1089/can.2018.0006. PMID: 30014038.
15. Stronati C. The design of upper secondary education across OECD countries: Managing choice, coherence and specialization. OECD. 2023 APR 3; Available from: https://one.oecd.org/document/EDU/WKP(2023)3/en/pdf [Last accessed: 2025 Feb 20].
16. Geppert J, Lietzow J, Hessel-Pras S, Kirsch F, Schäfer B, Sachse B. Usage and health perception of cannabidiol-containing products among the population in Germany: a descriptive study conducted in 2020 and 2021. BMC Public Health. 2023 Nov 23;**23**(1):2318. doi: 10.1186/s12889-023-17142-0. PMID: 37996800.
17. Casanova C, Ramier C, Fortin D, Carrieri P, Mancini J, Barré T. Cannabidiol use and perceptions in France: a national survey. BMC Public Health. 2022 Aug 29;**22**(1):1628. doi: 10.1186/s12889-022-14057-0. PMID: 36038869.
18. Lachenmeier DW, Habel S, Fischer B, Herbi F, Zerbe Y, Bock V, et al. Are adverse effects of cannabidiol (CBD) products caused by tetrahydrocannabinol (THC) contamination? F1000Res. 2019 Aug 8;**8**:1394. doi: 10.12688/f1000research.19931.7. PMID: 32117565.
19. Protano C, Valeriani F, Marotta D, Bargellini A, Bianco A, Caggiano G, et al. Assessing Undergraduates' Perception of Risks Related to Body Art in Italy: The SUPeRBA Multicenter Cross-Sectional Study. Int J Environ Res Public Health. 2021 Sep 1;**18**(17):9233. doi: 10.3390/ijerph18179233. PMID: 34501822.
20. Felnhofer A, Kothgassner OD, Stoll A, Klier C. Knowledge about and attitudes towards medical cannabis among Austrian university students. Complement Ther Med. 2021 May;**58**:102700. doi: 10.1016/j.ctim.2021.102700. PMID: 33677020.
21. Weisman JM, Rodríguez M. A systematic review of medical students' and professionals' attitudes and knowledge regarding medical cannabis. J Cannabis Res. 2021 Oct 12;**3**(1):47. doi: 10.1186/s42238-021-00100-1. PMID: 34641976.
22. Botella-Juan L, Amezcua-Prieto C, Morales-Suarez-Varela MM, Mateos-Campos R, Ayán-Pérez C, Molina AJ, et al. Impact of the COVID-19 Pandemic on the Evolution of Prevalence and Patterns of Cannabis Use among First-Year University Students in Spain—UniHcos Project. Int J Environ. Res Public Health. 2022 Sep 14;**19**(18):11577. doi: 10.3390/ijerph191811577. PMID: 36141846.
23. Alves R, Precioso J, Becoña E. llicit Drug Use among College Students: The Importance of Knowledge about Drugs, Live at Home and Peer Influence. J Psychoactive Drugs. 2021 Sep-Oct;**53**(4):329–338. doi: 10.1080/02791072.2020.1865592. PMID: 33382024.
24. European Monitoring Centre for Drugs and Drug Addiction. European Drug Report 2021: Trends and Developments. European Drug Report. 2021 Jun 9; Available from: https://op.europa. eu/en/publication-detail/-/publication/a3dd1033-fd56-11ea-b44f-01aa75ed71a1/language-en [Last accessed: 2025 Feb 20].
25. Cuttler C, Spradlin A, McLaughlin RJ. A naturalistic examination of the perceived effects of cannabis on negative affect. J Affect Disord. 2018 Aug 1;**235**:198-205. doi: 10.1016/j.jad.2018.04.054. PMID: 29656267.
26. Crippa JA, Guimarães FS, Campos AC, Zuardi AW. Translational Investigation of the Therapeutic Potential of Cannabidiol (CBD): Toward a New Age. Front Immunol. 2018 Sep 21;**9**:2009. doi: 10.3389/fimmu.2018.02009. PMID: 30298064.
27. Sholler DJ, Schoene L, Spindle TR. Therapeutic Efficacy of Cannabidiol (CBD): A Review of the Evidence from Clinical Trials and Human Laboratory Studies. Curr Addict Rep. 2020 Sep;**7**(3):405-412. doi: 10.1007/s40429-020-00326-8. PMID: 33585159.
28. Bhattacharyya S, Morrison PD, Fusar-Poli P, Martin-Santos R, Borgwardt S, Winton-Brown T, et al. Opposite effects of delta-9-tetrahydrocannabinol and cannabidiol on human brain function and psychopathology. Neuropsychopharmacology. 2010 Feb;**35**(3):764-774. doi: 10.1038/npp.2009.184. PMID: 19924114.

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Direct and indirect healthcare costs of ocular diseases in Italy: a literature review on glaucoma, diabetic retinopathy, and macular degeneration

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Keywords: Glaucoma; Diabetic retinopathy; Age-related macular degeneration; Economic Burden; Healthcare costs; Public health

Parole chiave: Glaucoma; Retinopatia diabetica; Degenerazione maculare legata all'età; Costi sanitari; Salute pubblica

Abstract

Background. *Glaucoma, diabetic retinopathy, and age-related macular degeneration impose substantial economic burdens on healthcare systems due to their high prevalence and chronic nature. Nevertheless, comprehensive Italian data is limited. This study aims to collect Italian evidence on the economic impact of these conditions to support more effective healthcare planning.*

Study Design. *Systematic review.*

Methods. *A systematic literature search was conducted in accordance with PRISMA guidelines across PubMed, Scopus, Web of Science, and EMBASE databases. Studies reporting cost evaluations of managing glaucoma, diabetic retinopathy, and age-related macular degeneration in Italy were included. Direct, indirect and non-medical costs were considered.*

Results. *The review included 23 studies exhibiting considerable heterogeneity in timeframes, regions, and economic evaluation approaches. For glaucoma, annual direct costs ranged from €788.70 for early-stage cases to €8,368.51 for advanced cases requiring surgery. Annual costs associated with diabetic retinopathy ranged from €4,050 to €5,799 per patient, depending on disease severity and treatment approach. The financial burden of age-related macular degeneration varied considerably, with costs ranging from €1,399.20 for early-stage cases to €3,973.30 for advanced stages. Although non-medical and indirect costs, such as lost productivity and caregiving expenses were less frequently assessed, they represented a significant contributor to the overall financial burden.*

Conclusions. *This study highlights the substantial economic burden ocular diseases place on the Italian healthcare system. Early intervention and preventive strategies could reduce the long-term costs of managing diabetic retinopathy and age-related macular degeneration. Further research into indirect costs and cost-effective interventions is necessary to support more efficient healthcare resource allocation.*

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Introduction

Many of the developed and developing countries are facing an unprecedented and rapid rise in the number of elderly people, leading to profound health and economic consequences (1). As Italy faces a rapidly ageing population, with individuals aged 65 and older expected to account for 35.9% of the population by 2050 (2), the country must confront the increasing prevalence of age-related chronic diseases, including ocular conditions such as glaucoma, diabetic retinopathy (DR), and age-related macular degeneration (AMD) (3). They are among the most common eye diseases leading to blindness and visual impairment in Italy and other developed countries (4,5).

These diseases not only impair vision and diminish quality of life (6) but also restrict opportunities for education and employment (7,8). Furthermore, the diagnosis and management of these chronic conditions impose a considerable financial burden on the National Healthcare Service (NHS). In Italy, it is estimated that approximately 550,000 individuals have been diagnosed with glaucoma; this corresponds to about 2% prevalence in population aged ≥40 years (9). DR is one of the most common complications of diabetes mellitus (DM) (10) and the leading cause of blindness in the working-age population (11,12). However, there is a lack of comprehensive data on the prevalence and incidence of legal blindness among diabetic patients, exacerbated by the absence of a national registry for individuals with DM. Epidemiological studies indicate that at least 30% of the diabetic population in Italy is affected by retinopathy, though significant regional heterogeneity exists (13). AMD also presents a major public health challenge. While recent Italian data on AMD incidence are limited, European studies estimate that among individuals aged 60 years and older, the prevalence of early or intermediate AMD is approximately 25.3%, and the prevalence of any late-stage AMD is around 2.4% (14).

The economic impact of these ocular diseases is multifaceted, encompassing both direct costs, such as medical treatment and hospital care, and non-medical and indirect costs, including lost productivity and caregiver expenses (7,15). Despite some available data, comprehensive national cost figures are fragmented and difficult to access. This lack of detailed and up-to-date information hinders effective healthcare planning and the optimal allocation of resources.

Given that the prevalence of glaucoma, DR, and AMD is expected to rise in the coming years, posing a significant burden on healthcare systems globally, the objective of this review is to provide a comprehensive and up-to-date overview of the direct and indirect healthcare costs associated with these conditions in Italy. The primary objectives are to provide an in-depth overview of the economic burden these ocular diseases impose on the Italian NHS, to identify gaps in the current knowledge, and to suggest areas for future research. By critically evaluating the available data, this review seeks to inform healthcare policy and resource allocation, ultimately contributing to the improved management of these increasingly prevalent ocular conditions within the context of Italy's ageing population.

Methods

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration number CRD CRD42024572796.

Literature search strategy

The literature search was conducted on PubMed/MEDLINE, Scopus, Web of Science (WoS), and EMBASE on July 24, 2024. Moreover, grey literature was also consulted to detect any potentially relevant articles. Additionally, manual searches were performed by reviewing the bibliographic citations. The search aimed to answer the question: "What are the current direct and indirect healthcare costs associated with managing glaucoma, diabetic retinopathy, and macular degeneration in Italy, and how have these costs evolved over time?". The search strategy combined Medical Subject Headings (MeSH) terms and title/abstract keywords. For glaucoma, diabetic retinopathy, and AMD, terms such as 'cost evaluation,' 'economic burden,' and 'Italy' were employed. The full search strategy, developed for each database, is available in supplementary table 1.

Eligibility criteria

Studies were selected based on the PEOS framework: Population (P), Exposure (E), Outcome (O), and Study design (S). Eligible studies were those involving patients with glaucoma, diabetic retinopathy, or age-related macular degeneration (population), and assessing the economic evaluations related to these ocular diseases, including direct,

non-medical and indirect (outcome), associated to the treatment and management of these diseases (exposure). Primary outcomes included cost data related to disease management (direct, indirect and non-medical costs). Secondary outcomes included the economic impact of different stages of disease severity and treatment modalities. In this review, we included both observational studies (cohort studies, case-control studies, cross-sectional studies) and economic evaluations employing simulation models and administrative database analyses, to enable a comprehensive mapping of cost dimensions. The search was restricted to studies published in Italian and English. Supplementary table 2 provides a detailed description of the criteria.

Study selection and data extraction

The study selection process was conducted in two stages. First, titles and abstracts of all identified records were screened independently by two reviewers using predefined eligibility criteria. Full-text articles of potentially eligible studies were then retrieved and assessed for inclusion. Discrepancies were resolved through discussion or by consulting a third reviewer. The study selection process was documented using a PRISMA flow diagram.

Data were extracted using a standardized template in Microsoft Excel (Microsoft Excel® for Microsoft 365 MSO, Redmond, WA, USA, 2019). The extracted data included: first author, year of publication, region where the study took place, time period, study design, ocular pathology, study type, study objective, sample size, age, sex and incidence and prevalence of included ocular diseases; data collection methods, follow-up, cost calculation methods, cost perspective, funding sources and main results, including average cost per patient, cost breakdown, sensitivity analysis, and cost-effectiveness results. Lastly, funding sources were also collected.

The data extraction template was piloted on three randomly selected studies to ensure consistency and reliability among the reviewers. Data extraction was performed independently by two reviewers, and discrepancies were resolved through discussion.

Quality assessment

The risk of bias in the included studies was assessed independently by two reviewers using the Newcastle-Ottawa Scale (NOS). This scale is specifically designed for evaluating the quality of non-randomized studies, such as cohort and case-control studies. The NOS assesses studies based on three main domains: selection of study groups, comparability of groups, and ascertainment of the outcome of interest. Each study is scored on a star system, with higher scores indicating lower risk of bias. The reviewers carefully examined each domain, assigning stars according to predefined criteria. To ensure a rigorous quality assessment of economic evaluations and simulation models included in this review, we applied the CHEERS checklist (Consolidated Health Economic Evaluation Reporting Standards). This tool was selected for its emphasis on transparency and adequacy in reporting, specifically addressing key components such as the validity of economic assumptions and the accuracy of modeling frameworks employed within each study. Additionally, the quality of the economic model was assessed using the ISPOR-SMDM Modeling Good Research Practices guidelines, covering 6 core domains: model transparency, structural assumptions, data sources and validation, internal consistency and validity, uncertainty and sensitivity analyses, and contextual relevance of model outcomes. Each domain was evaluated qualitatively for adequacy, partial adequacy, or inadequacy based on model rigor, data reliability, and alignment with real-world healthcare decision-making. Discrepancies between the reviewers' assessments were resolved through discussion, and if consensus could not be reached, a third senior reviewer was consulted to make the final decision. This thorough assessment process ensured a rigorous evaluation of the methodological quality of the included studies.

Data Synthesis

Given the expected high variability in study methodologies, cost definitions, and publication years, we chose to conduct a qualitative synthesis of the data rather than a meta-analysis. Our qualitative approach enables us to retain the diversity of findings across time periods, highlighting cost patterns and areas of heterogeneity without imposing potentially confounding adjustments. This choice aligns with the primary objective of this review: to map the range of direct, indirect and non-medical costs associated with ocular diseases in Italy, rather than to provide a pooled estimate that may not accurately reflect the variability across settings and times. Therefore, a narrative synthesis of the included studies was conducted, summarizing the study characteristics, cost data, and economic impacts. The results were tabulated and presented in text, with key findings illustrated in tables and figures.

Results

Study selection

A total of 304 articles were retrieved, of which 77 in PubMed/MEDLINE, 80 in Scopus, 100 in EMBASE and 47 in Web of Science. After removing duplicates, 165 studies were screened for eligibility by evaluating titles and abstracts, resulting in 45 studies selected for full-text assessment. Following this assessment, 23 studies (16-38) were included in the descriptive analysis. Figure 1 illustrates the study selection process.

Descriptive characteristics of included studies

The 23 studies included in this systematic review span various timeframes, regions, and ocular conditions, providing a broad perspective on the economic evaluations of glaucoma, DR, and AMD in Italy. Most studies (13/23, 57%) (17-20,24-27,29,31,32,35,38) cover focused on an observation period between 2000 and 2010, with a smaller proportion (35%) conducted after 2010 (16,22,23,28,30,33,34,36,37). The geographical distribution of the studies was diverse, with some offering regional insights and others presenting national data. Approximately 30% of studies (16,17,19,24,26,31,38) included international evaluations, providing a comparative lens across different healthcare systems.

Glaucoma was the most studied condition, representing 48% of the total studies (11 out

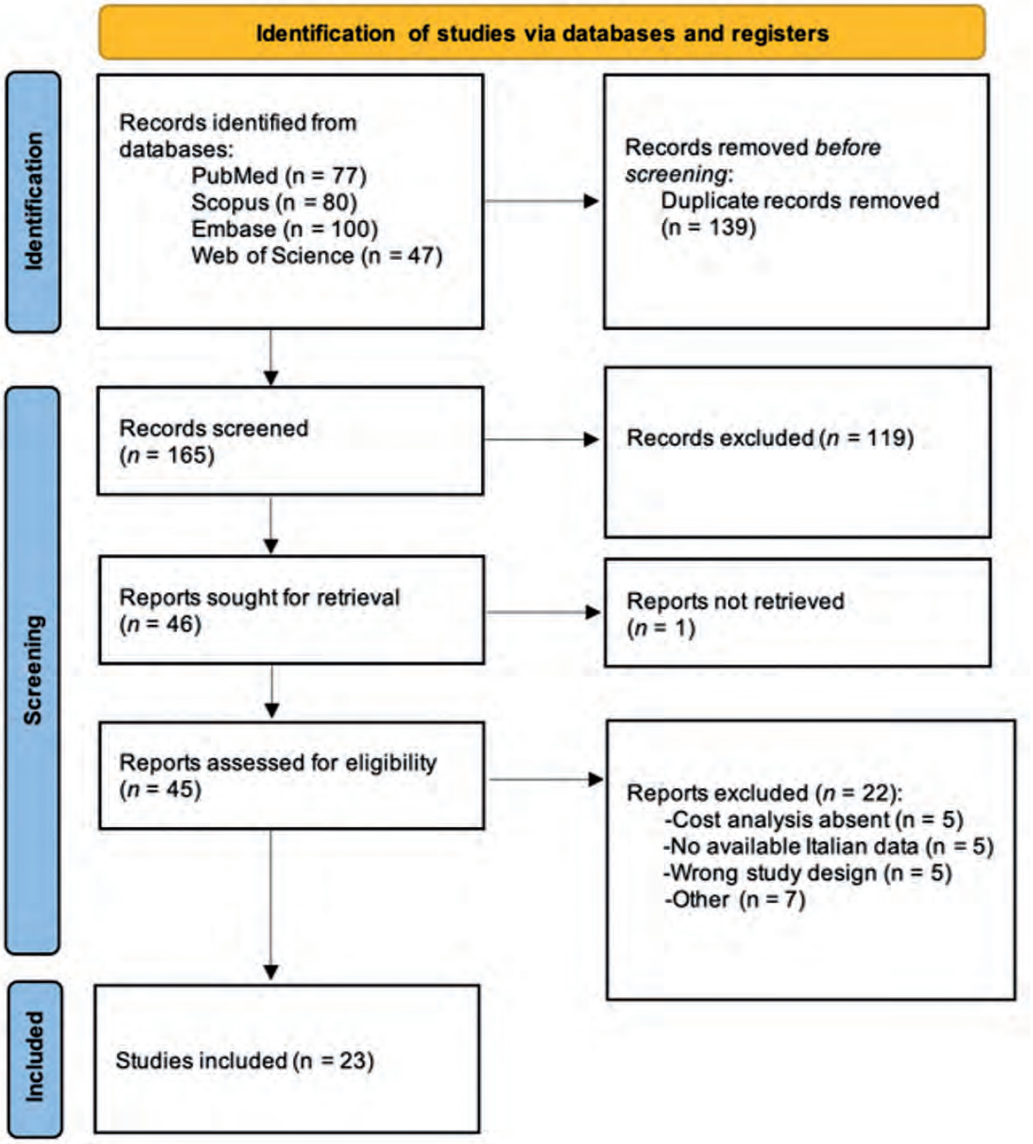

Figure 1 - Flow diagram depicting the screening process.

of 23), (18,19,21,22,26,27,29-31,34,38), while DR (28,35,36) and AMD accounted for 35% each (16,17,20,23,25,32,33,37). One study (24) encompassed at least two of these conditions.

Regarding cost assessment, the majority (35%, 8 out of 23) (16,17,20,25,29,31,37,38) focused on direct or indirect cost analysis, with an emphasis on resource utilization in the management of these chronic conditions. Cost-effectiveness analyses were employed in 22% of the studies (5 out of 23) (21,26,27,35,36) particularly for assessing treatment modalities and prevention strategies. Screening programs for DR were evaluated for their economic impact in 22% of the studies (5 out of 23) (24,28,32,35,36), with most highlighting the potential cost savings from early detection. Importantly, the assessment of costs in these studies primarily focused on direct costs, with 91% (21 out of 23) concentrating on expenses related to medical care, such as treatment and hospitalizations (16,18-31,33-38).Only two studies comprehensively assessed both direct and indirect costs, highlighting a gap in the literature regarding the broader economic burden, including loss of productivity and caregiver expenses (17,32). Descriptive characteristics of the included studies are provided in Table 1.

Overall, the descriptive characteristics of these studies demonstrate a focus on direct medical costs, particularly in relation to advanced disease stages, with a noticeable underrepresentation of indirect cost assessments. This emphasizes the need for future research to address the comprehensive economic impact of these ocular diseases, particularly as Italy's aging population continues to grow.

Demographic characteristics of the included population

This systematic review included studies with sample sizes ranging from 83 (18) to 18,161 (34) patients. The mean age of participants ranged from 58.6 years (35) to 77 years (17). The reviewed studies reported the prevalence of AMD ranging from 0.2% (33) in younger age groups to 13% (25) in older populations. The prevalence of DR among diabetic populations was approximately 29%, with an annual incidence between 2% and 6% (28). In Lombardy, 81% of diabetic patients, an estimated 36,780 individuals in 2014, were affected by DME (23). The prevalence of glaucoma in the Italian population aged 40 and over was approximately 2%. (22). Results are summarized in Table 1.

Table 1 - Descriptive characteristics of the included studies and demographic characteristics of the included population

Author and year (ref)	Region	Time period	Study design	Ocular pathology	Study type	Study objective	Sample size	Sex and age	Incidence and prevalence
Albrecht M et al, 2018 (16)	San Raffaele Hospital, Milan, Lombardy	2013 - 2015	Observational retrospective study	AMD, DME	Drug utilization and cost analysis of intravitreal anti-VEGF treatments (Ranibizumab and Aflibercept)	Evaluate the drug utilization patterns and associated direct costs of intravitreal anti-VEGF treatments in a real-world setting	2,117 patients (AMD: 60.5%, DME: 23.4%, mCNV: 7.1%, RVO: 9%)	Mean age: 69.9; 54.4% female	NA
Bandello F et al, 2008 (17)	France, Germany, Italy	2004	Cross-sectional observational study	AMD	Cost analysis	Investigate the costs of exudative AMD in patients actively treated at ophthalmology referral centers in France, Germany, and Italy	360 patients (France: 120, Germany: 126, Italy: 114)	Mean age: 77 years; 60% female	Prevalence in Italy: 1.1% in rural southern regions
Christensen TL et al, 2005 (18)	Italy (national level)	2005	Markov modelled pharmacoeconomic analysis	Glaucoma	Cost-minimization analysis	Analyze the costs and cost-savings of bimatoprost 0.03% as an alternative to filtration surgery for glaucoma patients in Italy over a 4-year period	83 adult patients with uncontrolled glaucoma scheduled for filtration surgery	Mean age: 66 years (± 11 years)	NA

(Segue Tab. 1)

De Natale R et al, 2011 (19)	France, Germany, Italy, Spain, UK	1995 - 2006	Longitudinal prescription analysis	Glaucoma	Prescription and economic impact analysis	Compare the evolution of prostaglandin analog and beta-blocker prescriptions across 5 European countries and evaluate the impact of healthcare regulations on glaucoma treatment costs and outcomes	Glaucoma-treated patients from various European databases	NA	NA
Denti C et al, 2002 (20)	Italy (national level)	1998	Observational retrospective study	AMD	Cost analysis of AMD from the payer's perspective	Evaluate the direct costs of patients affected by AMD in Italy from the perspective of the payers	497 patients divided into six subgroups: new and previous drusen, new and previous geographic atrophy, new and previous CNV	Mean age: 74 years	NA
Fea AM et al, 2021 (21)	Italy (national level)	NA	Cost-utility analysis	Glaucoma	Cost-effectiveness study comparing trabecular microbypass stents (iStent inject®) with cataract surgery vs. cataract surgery alone	Assess the cost-effectiveness of the iStent inject® device combined with cataract surgery compared to cataract surgery alone in patients with mild-to-moderate glaucoma	Patients with mild-to-moderate glaucoma in need of cataract surgery	Mean age: 64.7 years	Approximately 1 million individuals in Italy, with about 4500 new cases of blindness due to glaucoma registered each year
Ferrario L et al, 2020 (22)	Italy (national level)	2020	Economic sustainability analysis	Glaucoma	Economic evaluation of the XEN gel stent device for glaucoma treatment	Define economic sustainability of XEN gel stent in clinical practice across Italian regions, comparing costs with reimbursement tariffs	Approximately 550,000 glaucoma patients in Italy, representing 2% of the population over 40 years old	NA	550,000 people in Italy (2% of over 40 population)
Foglia E et al, 2017 (23)	Lombardy	2014 - 2015	Budget impact analysis	DME	Economic evaluation comparing alternative technologies to Ranibizumab	Evaluate the economic benefits of introducing additional alternative technologies for DME treatment in the Lombardy Region healthcare system	Patients with DME in Lombardy Region	NA	Diabetes prevalence in Lombardy: 5.40%. DME prevalence rate: 6.81%. Estimated 36,780 individuals with DME in 2014.
Gandjour A et al, 2002 (24)	France, Germany, Italy, The Netherlands, Sweden, Switzerland, and the UK)	2000 - 2001	European multicentre observational assessment	DR	Cost and quality comparison of preventive services for Type 2 diabetes mellitus	Evaluate potential differences in the process quality and costs of preventing secondary complications in patients with Type 2 diabetes mellitus across 7 European countries	Data from 188 European physician practices, assessing services for one hypothetical average patient and real patients	Aged 65 or younger	NA
Garattini L et al, 2004 (25)	Italy (Northern and Central)	1998 - 99	Multicenter, prospective 1-year study	AMD	Cost analysis of AMD in hospital ophthalmology departments	Calculate the resource utilization and direct medical costs of AMD in Italian hospital ophthalmology departments	476 patients, classified into three prognostic groups: Drusen: 23.7%, Geographic atrophy: 16.4%, CNV: 59.9%	Aged over 50 years	AMD affects adults from the age of 50 years, with higher prevalence in older age groups; almost 5% prevalence in those aged 75–84 years; 13% prevalence in those aged 85 or over

Holmstrom S et al, 2006 (26)	France, Germany, Italy, Spain, UK	2005	Cost-effectiveness analysis using a pharmacoeconomic model	Glaucoma	Cost-effectiveness analysis	Evaluate the cost-effectiveness of bimatoprost, latanoprost, and timolol in treating glaucoma in 5 European countries	Patients with primary open-angle glaucoma	Aged 18 years and older	NA
Hommer A et al, 2008 (27)	Europe (Italy, Spain, UK, Norway, Sweden)	2007	Cost-effectiveness analysis using a decision analytic model	Glaucoma	Cost-effectiveness analysis	Compare the cost-effectiveness of fixed-combination therapies (bimatoprost/timolol, travoprost/timolol, and latanoprost/timolol) in the treatment of glaucoma	Patients with open-angle glaucoma	NA	NA
Invernizzi A et al, 2016 (28)	Milan (Lombardy)	2012 - 2013	Single-center, single-blind observational study	DR	Feasibility and cost analysis of telemedical DR screening	Assess the feasibility of a telemedical approach for DR screening in the Italian population and to evaluate the advantages/disadvantages compared to standard slit-lamp funduscopic examination	1,281 patients with type 2 diabetes; 61% male	Mean age: 65.69 ± 12.64 years	Prevalence of DR in the diabetic population: approximately 29%; yearly incidence of DR: approximately 2%-6% |
Koleva D et al, 2006 (29)	Emilia-Romagna, Friuli-Venezia Giulia, Lombardy, Piedmont, Veneto, Lazio, Tuscany, Abruzzo, Apulia, Calabria, Sardinia, Sicily	2003	Multicenter observational study	Glaucoma	Cost analysis of glaucoma	Analyze the resource utilization and costs of glaucoma (staged by severity) in Italian ophthalmology departments	Patients with: Glaucoma: (273) or advanced Glaucoma (204)	65.1 years overall; 48.9% female	NA
Lazzaro C et al, 2023 (30)	Italy (national level)	NA	Cost-utility analysis	Glaucoma	Economic evaluation using a cost-utility analysis	Evaluate the cost-utility of STN1013001 compared to other latanoprost formulations	patients with glaucoma	57.60 years (range: 33.00;82.00)	Prevalence of open-angle glaucoma: 1.4%
Lee PP et al, 2007 (31)	USA, Europe (France, Germany, Italy, UK)	1995 - 2003	Retrospective medical chart reviews	Glaucoma	Cost analysis based on disease stage	Evaluate and compare treatment patterns, outcomes, and costs of glaucoma care in the United States and Europe	Total sample: 345 patients (151 US, 194 Europe)	Mean age: US: 66.3 years, Europe: 64.7 years US: 57.6% female, Europe: 47.9% female	US: glaucoma prevalence estimated at 2.47 million Americans in 2000 Italy: 1.4% of the population estimated to have glaucoma, with 540,000 undiagnosed cases
Muscio A et al, 2011 (32)	Italy (national level)	2005	Simulation and cost-benefit analysis	AMD, Glaucoma, DR	Economic impact analysis	Assess the financial effects of efficient prevention programs in Italy, providing empirical evidence that government investments in visual care prevention could reduce public spending.	Total number of blind individuals in Italy: 362,000 Blind individuals younger than 65 years: 61,000 Blind individuals in working age (15 – 64 years old): 56,000	Primarily individuals aged 15 to 64 years for working-age population and those older than 75 years	NA

Perrone V et al, 2022 (33)	The Marches, Lombardy, Calabria, Apulia, Lazio	2010 - 2017	Observational retrospective cohort study	AMD	Pharmaco-utilization of anti-VEGF drugs and cost analysis	Analyze pharmaco-utilization of anti-VEGF drugs and healthcare costs in AMD and other ocular diseases patients in Italy	Patients with anti-VEGF prescriptions	Aged ≥50 years	Prevalence of AMD (both wet and dry): between 0.2% and 5.6% in Europe, with 2.1% in Italy. Worldwide, 30–50 million people are affected by AMD
Perrone V et al, 2023 (34)	Apulia, Campania, Umbria, Lazio, Veneto	2010 - 2021	Observational retrospective study	Glaucoma	Real-world analysis	Evaluate characteristics, therapeutic paths, and economic burden of glaucoma patients treated with ophthalmic drops in Italy using real-world data	18,161 glaucoma patients	Mean age: 66.6 years; 56% female	Prevalence: 0.67% among study population, estimated 550,000 individuals in Italy
Porta M et al, 1999 (35)	Turin (Piedmont)	1993 - 94	Observational retrospective study	DR	Cost-effectiveness analysis of screening and treatment approaches	Analyze and compare the costs of screening and treating sight-threatening diabetic retinopathy in three different clinical settings	2,040 patients (Centre A: 493; Centre B: 500; Centre C: 1,076)	Mean ages: Centre A: 58.6 years, Centre B: 62.7 years, Centre C: 60.3 years Females: Centre A: 50.7%, Centre B: 51.4%, Centre C: 49.6%	Prevalence: DR: Centre A: 58.2%, Centre B: 74.7%, Centre C: 64.3%; Background DR: Centre A: 29.2%, Centre B: 12.3%, Centre C: 18.9%; Proliferative DR: Centre A: 1.2%, Centre B: 1.3%, Centre C: 3.4%
Scarpa G et al, 2016 (36)	Treviso (Veneto Region)	2012	Prospective study	DR	Cost-effectiveness analysis	Evaluate the feasibility and cost-effectiveness of a screening programme for DR using a nonmydriatic fundus camera in Treviso	498 diabetic patients in Ponzano, Treviso (340 accepted for screening)	Mean age: 68 years; 45% females	Prevalence of diabetes in Ponzano: 10%. Prevalence of DR among screened: 13%
Scuteri D et al, 2019 (37)	Calabria	2014 - 2017	Observational retrospective study	DR, AMD	Pharmacoutilization and cost analysis	Assess prevalence of DR and AMD, and pharmacoeconomic impact of ranibizumab treatment	Patients receiving clinical observation at "Mater Domini" University Hospital: 377 patients with AMD 183 patients with DR 185 patients with DME	Females: AMD: 51.2% (193/377), DR: 32.8% (60/183), DME: 26.5% (49/185), RVO: 49.6% (62/125)	NA
Traverso CE et al, 2005 (38)	Austria, France, Germany, Italy, UK	1995 - 2003	Multinational long-term observational study	Glaucoma	Cost analysis of glaucoma treatment based on disease severity	Estimate resource utilization and direct medical costs associated with long-term management of glaucoma of different severities in 5 European countries	194 patients with diagnoses of glaucoma, normal tension glaucoma, ocular hypertension, or glaucoma suspect	Mean age: 64.7 years (SD 12.1)	Prevalence: Italy: Approximately 50,000 people visually handicapped by glaucoma, 540,000 over 40 years had glaucoma, half undiagnosed Germany: Glaucoma third leading cause of blindness (1.6/100,000), 22.8/100,000 in those aged 75 and older

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; DME: Diabetic Macular Edema; EU: European, UK: United Kingdom; USA: United States of America. AMD: Age-related macular degeneration; DR: Diabetic retinopathy; DME: Diabetic Macular Edema; mCNV: myopic Choroidal Neovascularization; RVO: Retinal Vein Occlusion; SD: Standard Deviation; anti-VEGF (Anti-Vascular Endothelial Growth Factor).

Methodological approaches and funding sources in health economic evaluations

The studies included in this review employed various data collection methods. Administrative databases and registries were utilized in 30% of the studies (7 out of 23) (16,19,22,33,34,36,37), while 23% of the studies (6 out of 23)(17,20,25,27,28,35) relied on patient interviews and medical records (Table 2).

The follow-up durations exhibited considerable variation, ranging from 1 day to 36 years, with most studies (39%, 9 out of 23)(18–20,23–25,31,36,38) having a follow-up period of 1 to 5 years. Notably, two studies(17,32) did not include any follow-up period, as they were cross-sectional or simulation-based analyses.

Cost calculation methods were classified into three categories: bottom-up microcosting (35% of the studies)(17,18,20,24–27,29), Activity-Based Costing (ABC)(13%)(22,34,36) and Markov models (11.5%) (21,30). Additionally, a subset of studies (16,19,23,28,31-33,35,37,38) adopted a hybrid approach, integrating unit costs derived from tariffs or national pricing lists with the aforementioned methodologies. Regarding cost perspectives, most of the studies (87%, 20 out of 23) (16,18-22,24-31,33-38) were conducted from the National Health System (NHS) perspective. Most studies (65%, 13 out of 23) (16-18,21,24-27,29,31,33,34,38) reported external financial support, predominantly from pharmaceutical companies. The quality assessment using the NOS is presented in Table 2, while the results of the CHEERS checklist assessment and ISPOR evaluation are detailed in Supplementary Tables 3a and 3b.

Direct Costs

Glaucoma

The analysis of the literature on the direct costs of glaucoma revealed substantial variability influenced primarily by disease severity and the complexity of required medical interventions. Reported annual costs per patient range from approximately €788.7 for early-stage glaucoma to €8,368.51 for cases involving advanced surgical procedures such as the iStent inject combined with cataract surgery (21). Surgical interventions, particularly trabeculectomy and filtration surgery, emerged as the most significant cost drivers, with expenses reaching up to €2,121 for a single filtration surgery (18). Medication costs also play a substantial role, especially with treatments like

Table 2 - Methodological approaches and funding sources of included studies, and quality assessment.

Author and year	Data Collection Methods	Follow-Up	Cost Calculation Methods	Cost Perspective	Funding Sources	Quality Assessment
Albrecht M et al, 2018 (16)	The AIFA anti-VEGF monitoring registry and the reimbursement files from local health authorities	Median follow-up 224 days, (1 to 1,448 days)	Based on the number of injections and associated drug expenditures	NHS	Novartis Farma S.p.A.	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9
Bandello F et al, 2008 (17)	Patient interviews and medical records	None (cross-sectional study)	Medical costs based on national tariffs and market prices non-medical costs estimated from market prices and national tariffs	Societal perspective	Alcon France SA, Rueil-Malmaison, France	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9
Christensen TL et al, 2005 (18)	RCT and Delphi panel of Italian ophthalmologists	4 years	Unit costs obtained from Italian chart and tariffs review and pharmacy website; 3% discount rate applied	NHS	Allergan Inc.	Reported in Supplementary table 3b
De Natale R et al, 2011 (19)	IMS Health, UK-GPRD, and the Padova region pharmaceutical service	Longitudinal analysis from 1995 to 2006	Prescription data from various national and regional databases	NHS	None declared	Reported in Supplementary table 3a
Denti C et al, 2002 (20)	Patient records and billing information from seven centers	Retrospective analysis covering the trimester before patient enrollment (1999-2000)	Detailed analysis of direct costs based on tariffs of medical services and hospitalizations	NHS and patients	None declared	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Fea AM et al, 2021 (21)	Published literature, randomized clinical trials	Lifetime horizon adopted in the analysis	Costs calculated using a Markov model with four health states and a one-month cycle, considering only direct healthcare costs from the Italian NHS perspective	NHS	Glaukos	Reported in Supplementary table 3b

Ferrario L et al, 2020 (22)	Activity-Based Costing, data from various stages of patient care	Single follow-up ophthalmic visit	Activity-Based Costing	NHS	None declared	Reported in Supplementary table 3b
Foglia E et al, 2017 (23)	Real-life data from clinical practice, fine-tuned with the support of clinicians using Delphi methodology	12, 24, and 36 months	Based on number of injections and additional procedures	Lombardy Regional Healthcare Service	None declared	Reported in Supplementary table 3b
Gandjour A et al, 2002 (24)	Patient charts/medical records and estimates from physician offices	From May 2000 to February 2001	Bottom-up microcosting approach using reimbursement fees as unit costs in countries with detailed fee-for-service schedule (Germany, Italy, Switzerland)	NHS	German Ministry of Health	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Garattini L et al, 2004 (25)	Prospective data collection using a standardized questionnaire completed by ophthalmologists	1-year follow-up of patients	Costs calculated using NHS tariffs for consultations and diagnostic tests	NHS	Novartis Ophthalmics	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Holmstrom S et al, 2006 (26)	RCTs and a pharmacoeconomic model	1 year	Costs of medication and ophthalmologist visits included; other costs assumed equal among alternatives	NHS	Allergan R&D Europe	Reported in Supplementary table 3b
Hommer A et al, 2008 (27)	Retrospective analysis of clinical trial data	3 months	Medication costs based on 2007 market prices inclusive of VAT Clinical visit costs from national databases	NHS	Allergan R&D Europe	Reported in Supplementary table 3b
Invernizzi A et al, 2016 (28)	Routine diabetes visits and patient interviews	1 year	Based on minimum wage of a reading center reader and depreciation of the DRS	NHS	None declared	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9
Koleva D et al, 2006 (29)	Routine clinical practice data collected by ophthalmologists using predesigned questionnaires	1-year follow-up of patients	Micro-costing study in 5 centers, direct costs, and NHS tariffs for diagnostic tests, laser, and surgical interventions	NHS	Novartis Farma and Pharmacia Italia SpA	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Lazzaro C et al, 2023 (30)	Clinical studies and health economic modeling	5-year horizon with a 1-year cycle	Based on a Markov model with a 5-year horizon and 1-year cycle	NHS	Santen GmbH, München, Germany	Reported in Supplementary table 3b
Lee PP et al, 2007 (31)	Retrospective chart review with data abstraction by trained researchers	Minimum of 5 years continuous follow-up	Unit costs from publicly available health resource costing, reimbursement, or tariff sources Costs to the healthcare system, not out-of-pocket expenses for patients	NHS	Allergan, Inc.	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Muscio A et al, 2011 (32)	National statistics, labor economics, tax authorities, and interviews with representatives of IAPB Italia Onlus	None (simulation study)	Three-stage approach: Calculation of aggregate costs, estimation of individual average costs, simulation in capital budgeting	Societal perspective	None declared	Reported in Supplementary table 3b
Perrone V et al, 2022 (33)	Administrative databases	At least 12 months to 3 years	Using DRG tariffs and Italian NHS purchase prices	NHS	Novartis Farma S.p.A.	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Perrone V et al, 2023 (34)	Administrative databases	From index date to end of data availability or death	Activity-Based Costing	NHS	Allergan SpA, an AbbVie company	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9

Porta M et al, 1999 (35)	Case notes, patient questionnaires, hospital records	1993-1994, follow-up until Jun 1995	Data from three diabetes clinics in Turin	NHS and patients	None declared	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9
Scarpa G et al, 2016 (36)	Primary and secondary diagnosis databases, hospitalizations, drugs, and healthcare procedures	1 year	Activity-based costing analysis andbudget impact analysis; 2015 Italian Outpatients and Hospital Admissions Reimbursement Tariffs; NHS price list	NHS	None declared	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9
Scuteri D et al, 2019 (37)	Ophthalmology ward database	January 2014 to June 2017	Based on the number of ranibizumab injections	NHS	None declared	Selection: 3/4 Comparability: 0/2 Outcome: 3/3 Total Score: 6/9
Traverso CE et al, 2005 (38)	Retrospective chart review	Minimum 5 years	Unit costs from national sources: France (PMSI), Germany (EBM and GOA), Italy (CEIS), UK (NHS costing manual)	NHS	Allergan Inc.	Selection: 3/4 Comparability: 1/2 Outcome: 3/3 Total Score: 7/9

AIFA: Agenzia Italiana del Farmaco; anti-VEGF (Anti-Vascular Endothelial Growth Factor; NHS: National Health Service; RCT: Randomized Controlled Trial; IMS Health: Information Medical Statistics Health; UK-GPRD: United Kingdom General Practice Research Database; VAT: Value-Added Tax; DRS: Diabetic Retinopathy Study; DRG: Diagnosis-Related Group; IAPB Italia Onlus: International Agency for the Prevention of Blindness, Italian branch; PMSI: Programme de Médicalisation des Systèmes d'Information (France); EBM: Einheitlicher Bewertungsmaßstab (Germany); GOA: Gebührenordnung für Ärzte (Germany); CEIS: Centro di Economia Internazionale e Sviluppo (Italy).

bimatoprost, which, although more cost-effective over time compared to surgery, still represents a significant ongoing expense (27). Furthermore, managing complications, such as stent obstruction, adds additional financial burden, with costs reported at €1,522 per incident (21). Notably, the analysis revealed a clear correlation between increasing disease severity and rising costs, particularly in advanced stages where the need for frequent hospitalizations and complex treatments drives expenses upwards to €1,054.9 annually (29). Results are summarized in Table 3.

Diabetic retinopathy

Direct costs for DR include all diagnostic tests for detecting the disease, follow-up costs, and medical therapies to control and prevent progression, including laser therapy. Early diagnosis significantly impacts cost estimates, with screening campaign costs relatively low but potentially influencing future avoidable costs (ranging between Italian Lira (ItL) 64,857 and 86,044) (35). Screening programs conducted within specialized diabetes clinics were notably more cost-effective compared to those involving external ophthalmologists, with standardized costs per 1,000 screenings ranging from ItL 65,916 to ItL 81,545, depending on the center (35). The implementation of fundus photography screening, at €4.45 per session, proved to be a cost-saving alternative to standard funduscopic examination (€7.90 per session), thereby enhancing screening efficiency and reach (28). Including cost-effectiveness analyses of screening interventions in this review highlights the crucial role of prevention in the overall management of DR. Screening programs not only help improve patient health by enabling early intervention but also yield substantial financial benefits by averting the progression to severe stages of the disease, which would incur higher treatment costs. For instance, comprehensive screening programs significantly outperformed the "do nothing" strategy, yielding savings of €271,543.32 (−13.71%) by reducing the incidence of blindness and associated healthcare costs (36). Treatment with Anti-Vascular Endothelial Growth Factor (anti-VEGF) agents, particularly ranibizumab, represented a major cost driver, with per-patient annual costs decreasing from €5,799.84 in 2014 to €4,050.00 in 2017, reflecting reduced treatment frequencies (37) .

Age-related macular degeneration

Direct costs for AMD include expenses for ophthalmological visits, in-depth ocular exams (e.g.,

Table 3 - Summary of the main results for each included study

Disease Type	Author and Year	Cost Breakdown	Sensitivity Analysis	Average cost per patient
AMD	Albrecht M et al, 2018	Drug costs and injections	Monocentric design limits generalizability: differences in approval times may affect treatment	AMD: €2,787-2,899, DME: €3,010-3,231
	Bandello F et al, 2008	Medical costs (Consultations, Examinations, Hospitalizations, Medications, Treatments), Non-medical costs (Visual aids/services, Paid assistance, Transportation)	Costs vary significantly by severity level	€3,001.50 (Total Costs); Range: Level 1: €1,399.20 – Level 4: €3,973.30
	Denti C et al, 2002	Medical costs, non-medical costs	NA	€33,371 - €968,060 (depending on the scenario)
	Foglia E et al, 2017	Drug costs, diagnostic tests, specialist visits, procedure costs for injections	Various retreatment rates and market shares analyzed	First Year: €1,562 (Bevacizumab) – €4,276 (Aflibercept); Over 36 months: €7,042 (Dexamethasone)
	Garattini L et al, 2004	Specialist consultations, diagnostic procedures, hospitalizations, laser therapy, medications	NA	Drusen: €158.1; Geographic atrophy: €147.9; CNV: €540.1
	Muscio A et al, 2011	Healthcare costs for screening and treatment vary depending on disability progression	Simulation: varying disability levels	Scenario 1: €871.41 (glaucoma), €1,169.04 (AMD), €291.53 (diabetic retinopathy), €1,575.16 (cataracts)
	Perrone V et al, 2022	Drug prescriptions; hospitalizations; outpatient specialist services; diagnostic tests	NA	2014: €5799.84; 2015: €3284.01; 2016: €3212.84
	Scuteri D et al, 2019	Intravitreal injections, drug costs, procedure costs	NA	2014: €5,799.84; 2015: €5,388.77; 2016: €4,759.56; 2017: €4,050.00
DR	Gandjour A et al, 2002	Preventive care for Type 2 diabetes	NA	€282.50 (5 years)
	Invernizzi A et al, 2016	Fundus photography, standard funduscopic exam	NA	Fundus Photography: €4.45 per session; Standard Funduscopic Exam: €7.90 per session
	Porta M et al, 1999	Screening costs, total costs of treated patients	Sensitivity to prevalence and cost structure	Screening: €64,857 – €86,044 (ItL per person/year); Treated patients: €1,131,594 – €1,879,827 (ItL/year)
	Scarpa G et al, 2016	Screening Phases, Ranibizumab + Laser Therapy, Dexamethasone	Variation in screening attendance and examination rates	NA

Glaucoma	Christensen TL et al, 2005	Visit to ophthalmologist, filtration surgery, beta-blocker, bimatoprost	Transition probabilities, varying time horizons	After 1 year: €3,566 (surgical) vs. €1,576 (bimatoprost); After 4 years: Bimatoprost costs 19.6% less than surgery
	De Natale R et al, 2011	Medication and treatment persistence	NA	NA
	Fea AM et al, 2021	Surgeries, medications, adverse events	One-way deterministic and probabilistic sensitivity analyses performed	iStent inject® + Cataract Surgery Group: €8,368.51 per patient per year; Cataract Surgery Alone Group: €7,134.71 per patient per year
	Ferrario L et al, 2020	XEN Gel Stent Surgery, day hospital, trabeculectomy	NA	XEN Gel Stent Surgery: €2,297.99; Day Hospital: €1,653.59; Trabeculectomy: €1,236.44
	Gandjour A et al, 2002	Preventive care for Type 2 diabetes	NA	€282.50 (5 years)
	Holmstrom S et al, 2006	Medication costs, ophthalmologist visit	Results robust across ±10% variation	€284.34 per year (Timolol + Bimatoprost)
	Hommer A et al, 2008	Medications per month, ophthalmologist visits	Varying discontinuation rates, medication unit costs	€116.66 (BT or TT) -€119.36 (LT) for 3 months
	Koleva D et al, 2006	Drugs, ophthalmologic consultations, diagnostic tests, hospital admissions	NA	€572 (Ocular Hypertension) - €1,054.9 (Advanced Glaucoma)
	Lazzaro C et al, 2023	Drug costs, diagnosis, follow-up, management, health states over 5 years	One-way, Probabilistic and scenario sensitivity analyses	+€57.60 over 5 years (STN1013001 vs. Latanoprost)
	Lee PP et al, 2007	Surgery vs. non-surgery; medication vs. no medication	NA	€2,943.83 per year (all stages of glaucoma)
	Perrone V et al, 2023	Drug expenditure, hospitalizations, outpatient services	One-way, probabilistic, and scenario-based sensitivity analyses	Costs from 2010 to 2021: €1,725 (2010) - €1,950 (2021)
	Traverso CE et al, 2005	Office visits, glaucoma exams, visual fields, glaucoma surgeries, cataract extractions, medications	NA	Stage 0: €153; Stage 1: €386; Stage 2: €421; Stage 3: €669; Stage 4: €791; Stage 5: €712

AMD: Age-related Macular Degeneration; DME: Diabetic Macular Edema; NA: Not Applicable

angiography), hospitalization, emergency room visits, and specific therapies (photocoagulation, photodynamic therapy, and innovative drugs). The annual per-patient costs reflect the intensity of care required, showing a 4% increase from 2014 to 2015, primarily driven by the frequency of intravitreal injections, which averaged approximately four per patient per year (16). The severity of AMD is a critical determinant of cost, as highlighted by Bandello et al (17), where annual costs range significantly from €1,399.2 for less severe cases to €3,973.3 for advanced stages, indicating that disease progression substantially inflates healthcare expenditures. Direct medical costs, particularly for hospitalizations, surgeries, and laser therapies, represent the bulk of the expenses, with surgical cases incurring costs as high as €2,843.10 per patient (20). Choroidal Neovascularization (CNV) further exacerbates costs, with associated annual expenses reaching €540.1 per patient, underscoring the financial impact of this complication (25). Additionally, economic models suggest that without effective blindness prevention strategies, the total annual costs for AMD could escalate significantly, potentially reaching €24,741.13 per patient in cases of total disability (32). Pharmacological management, particularly with anti-VEGF therapies such as ranibizumab, constitutes a substantial part of these costs. However, a reduction in treatment frequency has been linked to a decrease in per-patient costs, from €5,799.84 in 2014 to €4,050.00 in 2017, indicating the potential for cost savings with optimized treatment protocols (37) .

Denti et al (20) separately evaluated private healthcare costs in macular degeneration (out-of-pocket costs for private visits and over-the-counter medications), with annual private visit expenses averaging €29.90 (14% of the total) and medications at €8.60 (4.1% of the total). Garattini et al. (25) estimated the average annual private expenditure for a macular degeneration patient at €51.70. Results are summarized in Table 3.

Non-medical costs and indirect costs

Non-medical costs for all pathologies were analyzed by two studies, including expenses for visual aid devices, insurance assistance, housing adaptation, transportation, and social assistance.

Bandello et al (17) provided a comprehensive analysis of both medical and non-medical expenses, demonstrating the escalating financial impact as the disease progresses. Non-medical costs refer to expenses incurred by patients that are not directly related to medical treatments. These costs include out-of-pocket expenses for vision aids, transportation, and support services. Notably, the study revealed that non-medical costs, such as those associated with social security and other out-of-pocket expenses, varied markedly with disease severity. For instance, patients with better visual acuity (Best Eye (BE) ≥20/40) incurred non-medical costs up to €1,745.10, contributing to a total annual cost of €3,761.90 per patient. In contrast, in more advanced stages (BE <20/40, Worst Eye (WE) <20/200), non-medical costs were slightly lower at €1,539.30, yet the total annual cost per patient reached €3,973.30. This suggests that while non-medical costs may decrease slightly in later stages, the overall financial burden remains high, due to the increasing medical costs.

Muscio et al (32) further expanded on this by simulating the broader economic impact of AMD through various hypothetical scenarios, particularly focusing on the costs associated with the absence of effective blindness prevention programs. Their findings indicated that as AMD progresses, the non-medical costs and indirect costs - including social security payments, tax allowances, and productivity losses - can escalate significantly. In a scenario of partial disability, the total indirect costs were calculated to be €24,741.13 annually, with substantial contributions from social security expenses and productivity losses. This analysis underscores the critical role of indirect costs in the overall economic assessment of AMD, highlighting the necessity for comprehensive management strategies that address both direct and indirect financial impacts. Table 3 provides a summary of the results from the analysis.

Studies' quality assessment

The quality assessment of the studies reviewed indicates a generally robust methodological approach. Overall, the total scores ranged from 5 to 7 (out of 9 maximum points), with 9 studies (16,17,19,22,23,28,34,36,37) scoring 6 and 11 studies (18,20,24–27,29,31,33,35,38) achieving 7 points, suggesting that, while most of the studies had solid methodological quality, there is room for improvement in comparability and selection criteria.

Most of the studies (20 out of 23) (16–20,22–29,31,33–38) got a good rating for how participants were selected, scoring 3 out of 4. However, the scores for how well the studies handled confounding factors varied more. Half of the studies (10 studies) didn't

control for these factors well and scored 0 out of 2 (16,17,19,22,23,28,30,34,36,37), while the other half (12 studies) did a better job and scored 1 out of 2(18,20,21,24–27,29,31,33,35,38). The Outcome Score was consistently high, with all 23 studies receiving 3 out of 3, demonstrating strong and reliable outcome measurements. Results of quality assessment are reported in Table 2.

Discussion

Main Results

This systematic review aimed to evaluate the economic burden of three major ocular diseases: glaucoma, diabetic retinopathy, and age-related macular degeneration. The review included a total of 23 studies. Our findings underscore the significant variability in direct, indirect and non-medical costs associated with these conditions, influenced primarily by disease severity, treatment modalities, and the healthcare settings in which patients are managed. These findings underscore the complex economic burden that these ocular diseases impose on the Italian NHS and highlight critical areas where targeted interventions could potentially yield significant cost savings.

Most of the studies were conducted between 2000 and 2010, primarily in northern Italian regions (Piedmont, Lombardy, and Veneto). Despite this heterogeneity, costs ranged from approximately €788.7 per year (29) (direct costs for managing early-stage uncomplicated glaucoma) to €24,741.13 per year (32) (including both direct and indirect costs for diabetic retinopathy with visual disability).

Due to the significant variability in cost estimates, diagnostic methods, and therapeutic approaches among the included studies, calculating an average cost for the three conditions is methodologically unreliable. Consequently, any average cost evaluation would likely be an oversimplification, and the interpretation of these data should be cautious. The only reliable comprehensive costs derived were those for individual conditions or blindness, a common outcome of all three diseases.

The analysis of glaucoma-related costs highlighted substantial variability, with annual direct costs ranging from approximately €788.70 (29) for early-stage glaucoma to over €8,368.51 (21) for advanced cases requiring surgical interventions. Surgical procedures, particularly trabeculectomy and filtration surgery, are identified as major cost drivers, with individual surgeries costing up to €2,121(18). Additionally, medication costs, especially for drugs like Bimatoprost, represent a significant ongoing financial burden, although they may be more cost-effective in the long run compared to surgical options (18). This finding is consistent with other studies (38–40) that have documented the high costs associated with long-term medication use in glaucoma management. The variability in costs also reflects the diversity of treatment regimens and the progression rates of the disease. The clear correlation between increasing disease severity and rising costs emphasizes the importance of early intervention and effective disease management strategies to minimize the economic impact (17,32,38). Effective cost management strategies should focus on optimizing pharmacological therapies and considering the cost-benefit ratio of early surgical interventions.

For DR, the direct costs are a significant component of the overall expenses for managing diabetes, given its nature as a complication of the primary disease. They are predominantly linked to diagnostic tests, ongoing monitoring, and treatment interventions such as laser therapy. Early diagnosis and regular screening play crucial roles in mitigating these costs by preventing the progression of the disease. The costs associated with anti-VEGF treatments, particularly ranibizumab, have been shown to decrease over time, reflecting reduced treatment frequencies and improved management protocols (37). Despite these reductions, the treatment of DR remains a significant financial burden on the healthcare system, underscoring the need for cost-effective preventive measures. Indeed, the cost of screening programs for DR is relatively low compared to the long-term costs associated with disease progression. Several studies from the dataset provide valuable insights into the economic benefits of early detection. The standardized costs for 1,000 screenings ranged from ItL 65,916 to ItL 81,545, depending on the center, illustrating the economic advantage of centralized, specialized care in comparison to external ophthalmologists. In terms of screening technologies, fundus photography, priced at €4.45 per session, emerged as a cost-saving alternative to traditional funduscopic exams, which cost €7.90 per session.

Regarding glaucoma, Christensen *et al* (18) conducted a cost-minimization analysis at a national level in Italy, showing that early intervention through screening can be highly cost-effective, particularly in specialized diabetes clinics. In particular, De Natale *et al* (19) found that implementing systematic screening

could reduce healthcare costs by €271,543.32 (a 13.71% reduction), primarily by decreasing the incidence of blindness and the high costs associated with late-stage disease management. These findings strongly support the prioritization of early detection programs for both DR and glaucoma. In summary, the data from the included studies illustrate that investing in early screening programs, especially those utilizing cost-effective methods like fundus photography, can lead to substantial long-term savings. Policymakers should focus on expanding such programs to achieve both economic benefits and improved patient outcomes by preventing the progression of diabetic retinopathy and its associated complications.

Similar results for AMD were found by Denti *et al* (20), who analysed the direct costs of ocular pathologies in Italy, suggesting that the introduction of more efficient screening methods could significantly reduce overall screening costs, while extending the reach of preventive care. Moreover, comprehensive screening programs have been shown to yield significant cost savings over a "do nothing" approach. Annual per-patient costs have been observed to increase from €2,787 to €2,899 (16) with the frequency of intravitreal injections being a significant factor. Advanced stages of AMD, particularly those involving CNV, are associated with markedly higher costs, reaching up to €3,973.3 (17) per patient annually. The financial impact of AMD is further exacerbated by the high costs of hospitalizations, surgeries, and specialized treatments such as laser therapies. The findings suggest that while the introduction of anti-VEGF therapies has provided a means of managing the disease, the overall cost burden remains substantial, particularly in advanced stages of AMD.

No data are available in the literature for the average cost per patient for the three conditions combined, making such evaluations impossible. The only available data pertain to the aggregated annual costs for "Diseases of Social Importance" (as defined by the World Health Organization (WHO) in 2006, including cataracts) in Italy, estimated by Muscio *et al* (32). This study calculated indirect costs from social security benefits, mobility subsidies, civil service assistance, and productivity loss, amounting to approximately €6.48 billion annually. This includes 44% for medical care (direct costs), 16% for social security subsidies, 2% for tax deductions, 1% for education costs, 5% for other benefits, and 32% for productivity loss.

The review also revealed considerable non-medical costs associated with all the three ocular diseases, encompassing expenses for visual aids, insurance assistance, housing adaptations, transportation, and social aids. Two key studies (17,32) provide insights into these costs, particularly for AMD, approaching from different perspectives and methodologies. Bandello *et al* (17) demonstrated that non-medical costs vary significantly with disease severity, with total annual costs per patient ranging from 3,761.9 to €3,973.3, depending on the stage of AMD. Muscio *et al*.'s (32) simulation study emphasizes the potential for significant increases in indirect costs as the disease progresses to more severe stages. The scenarios they modelled demonstrate how, in the absence of effective preventive measures, indirect costs such as social security payments and productivity losses could escalate dramatically, especially in cases of partial or total disability. The study estimated that total indirect costs could reach as high as €24,741.13 annually in cases of total disability, driven primarily by social security payments and productivity losses. These findings underscore the importance of considering both direct and indirect costs in the economic assessment of ocular diseases, as the latter can substantially contribute to the overall financial burden. Addressing these costs requires a comprehensive approach that includes support for visual aids, social services, and workplace adaptations to maintain productivity and quality of life for affected individuals.

The studies included in this review cover a wide temporal range, each reflecting different healthcare policies, diagnostic technologies, and economic contexts relevant to their specific periods. Attempting to harmonize or adjust these costs to a common base year would risk losing the nuances and temporal trends inherent to each study.

Interpretation of results, practical implications, future research

The management of glaucoma, DR, and AMD in Italy largely aligns with protocols established across the entire European Union. A detailed overview of approved medications and treatment strategies, reported in Supplementary Table 3, highlights the reliance on long-term treatments such as topical eye drops for glaucoma (e.g., Bimatoprost, Latanoprost, Timolol) and anti-VEGF agents for DR and AMD (e.g., Ranibizumab, Aflibercept, Bevacizumab). These therapies, while effective, require sustained administration and frequent monitoring, contributing significantly to the direct medical costs, particularly in outpatient settings. The introduction of newer agents such as Brolucizumab (Beovu) and Faricimab

(Vabysmo) for AMD reflects advancements in treatment options, potentially impacting both the costs and frequency of treatments due to varying maintenance phases. Additionally, therapies like Verteporfin (Visudyne) used in photodynamic therapy for specific AMD subtypes offer distinct approaches that may influence cost structures due to their combination of intravenous drug administration and laser activation, demanding specialized care.

Given that these chronic conditions require long-term treatment, the cumulative cost of care—both direct (e.g., medication, monitoring) and indirect (e.g., loss of productivity, caregiver burden)—is substantial. This further underscore the need for healthcare systems to consider patient-specific factors such as comorbidities and the potential for more intensive outpatient monitoring, as they may increase the resource utilization and associated costs. In this perspective, European countries, the three conditions under review are considered priorities at European level (41). Epidemiologically, in 2020, an estimated 596 million people had distance vision impairment worldwide, of whom 43 million were blind. However, encouragingly, more than 90% of people with vision impairment have a preventable or treatable cause with existing highly cost-effective interventions. By 2050, population ageing, growth, and urbanisation might lead to an estimated 895 million people with distance vision impairment, of whom 61 million will be blind (42). Action to prioritise eye health is needed now.

Despite the expected increase in the frequency of these conditions and associated disorders, underdiagnosis of ocular issues, particularly in the elderly, remains a significant problem, leading to blindness (32). According to INPS (Istituto nazionale della previdenza sociale, in English National Institute for Social Security) data, in 2023, there were 108, 416 blind individuals in Italy, with a markedly uneven distribution (e.g., Sicily with 14,244 blind individuals, prevalence 2.96‰; Lombardy with 12.535, prevalence 1.26‰) (43). These data refer to individuals with absolute or partial blindness (visual acuity not exceeding 1/20 in both eyes with correction) recognized by the Italian social security institution (INPS), making them eligible for pensions and allowances (44–46). Social security costs are significant because, for all three analyzed conditions, annual direct costs for disease management are substantially lower than indirect costs. Indirect costs mainly stem from social security interventions and productivity loss. Disabilities during working age significantly increase these costs, particularly for diabetic retinopathy, the leading cause of vision loss in working-age individuals in industrialized countries (ages 20-65) (47).

Regarding diabetes, WHO projects a 54% increase in cases in industrialized countries between 2000 and 2030 (48). In Italy, diabetes has been on the rise, with prevalence and incidence expected to continue increasing in those over 30 years old. Without preventive measures, diabetes and diabetic retinopathy will remain major problems in Italy and worldwide, where patient education and healthcare providers' training are crucial for risk management. Implementing secondary prevention campaigns is also highly effective in reducing costs and improving public health (28).

These primary and secondary prevention initiatives are strongly recommended (49), especially considering the Italian demographic trend, with an increasing elderly population (23.2% over 65 today, expected to reach 35% by 2050). The aging population will raise the average age from 45.7 years in 2020 to 49.7 years in 2040, alongside an increase in elderly individuals living alone, potentially increasing care needs. As demonstrated by Muscio et al. (32), early diagnosis through screening can reduce both disability risk and disease management costs, estimating a 9-34% reduction of the €4.376 billion annually spent by the Italian government on medical care, social security subsidies, tax deductions, education costs, and other benefits related to visual disability.

These findings highlight the growing economic burden posed by glaucoma, DR, and AMD in Italy. As the aging population grows, the financial strain on the NHS will intensify. Addressing these costs will require innovative healthcare strategies, particularly in preventive care and the optimization of treatment protocols to mitigate long-term expenses. Nevertheless, given the high costs associated with advanced disease stages, prioritizing early detection and preventive measures, such as regular screenings and patient education, could substantially reduce the financial burden on the NHS. Overall, the success of ocular prevention interventions depends on the availability, accessibility, affordability, and acceptability of dedicated services. Future research should focus on identifying barriers to these interventions and providing evidence on the economic burden of the reviewed conditions.

Limitations and strengths

Several limitations of this review should be considered before generalizing the results. The

included studies are heterogeneous in objectives and cost evaluation methodologies, making comparisons challenging. Many studies (57%, 13 out of 23) (17–20,24–27,29,31,32,35,38) were published before 2010 and considering medical advancements in diagnostic protocols and new therapies, the data might no longer be current. The possibility of drug price changes, inflation, and purchasing power should also be considered. Additionally, one study (35) performed before 2000 reported costs in Italian Lira or ItL instead of Euro (EUR,). Moreover, systematic reviews are subject to several common limitations. One relevant issue is the heterogeneity of included studies, which can differ widely in design, population characteristics, and methodologies, making result comparison challenging. Additionally, publication bias may occur when studies with positive outcomes are more likely to be published, potentially skewing the review's findings. The quality of evidence can be compromised by biases present in the primary studies, and the reliance on available literature may result in the exclusion of relevant data. These limitations must be acknowledged to ensure accurate interpretation of results and informed decision-making.

However, a strength of this research lies in its rigorous methodology, allowing the inclusion of 23 studies only. In the absence of updated and specific publications on this topic in Italy, this report provides a first attempt to evaluate the direct, indirect and non-medical costs of three major causes of visual disability and blindness in industrialized countries.

Conclusions

Considering the Italian epidemiological context, with an expected increase in the frequency of the three reviewed conditions in the general and elderly populations, a similar growth in direct and indirect costs can be anticipated. The review successfully highlights a range of costs for these conditions, though it is limited in evaluating expenditure trends, as a detailed predictive analysis requires a mathematical model beyond a literature review. In the future, it will be essential for patients to have access to structured diagnostic-therapeutic pathways, ensuring early diagnosis for optimal disease management, preventing complications, disease progression to advanced stages, and the need for high-cost (surgical) treatments and visual disability.

Riassunto

I costi sanitari diretti e indiretti delle malattie oculari in Italia: una revisione della letteratura su glaucoma, retinopatia diabetica e degenerazione maculare

Background. Il glaucoma, la retinopatia diabetica e la degenerazione maculare legata all'età impongono sostanziali oneri economici ai sistemi sanitari a causa della loro elevata prevalenza e natura cronica. Tuttavia, dati italiani complessivi sono attualmente limitati. Questo studio si propone di analizzare in modo approfondito i dati disponibili sull'impatto economico di queste condizioni, al fine di supportare una pianificazione sanitaria più efficiente ed efficace.

Disegno dello studio. Revisione sistematica.

Metodi. È stata effettuata una ricerca sistematica della letteratura in conformità alle linee guida PRISMA, utilizzando i database PubMed, Scopus, Web of Science ed EMBASE. Sono stati inclusi studi che riportavano valutazioni economiche nella gestione del glaucoma, della retinopatia diabetica e della degenerazione maculare legata all'età in Italia, considerando sia i costi diretti sia quelli indiretti.

Risultati. La revisione ha incluso 23 studi che mostrano una notevole eterogeneità in termini di periodi temporali, aree geografiche e approcci metodologici nelle valutazioni economiche. Per il glaucoma, i costi diretti annuali variavano da €788,70 per i casi in stadio iniziale a €8.368,51 per i casi avanzati che richiedevano interventi chirurgici. I costi annuali associati alla retinopatia diabetica oscillavano tra €4.050 e €5.799 per paziente, in funzione della gravità della malattia e dell'approccio terapeutico adottato. L'onere finanziario della degenerazione maculare legata all'età presentava variazioni significative, con costi che andavano da €1.399,20 per i casi in stadio iniziale a €3.973,30 per gli stadi avanzati. Sebbene i costi indiretti, come la perdita di produttività e le spese di assistenza, siano stati meno frequentemente valutati, essi rappresentano comunque un contributo rilevante al carico economico totale.

Conclusioni. Questo studio evidenzia il considerevole onere economico che le patologie oculari impongono al sistema sanitario italiano. L'implementazione di interventi precoci e strategie preventive potrebbe ridurre i costi a lungo termine nella gestione della retinopatia diabetica e della degenerazione maculare legata all'età. Sono necessarie ulteriori ricerche sui costi indiretti e su interventi costo-efficaci per supportare un'allocazione più efficiente delle risorse sanitarie.

References

1. Atella V, Piano Mortari A, Kopinska J, Belotti F, Lapi F, Cricelli C, et al. Trends in age-related disease burden and healthcare utilization. Aging Cell. 2019 Feb;**18**(1):1-8. e12861. doi: 10.1111/acel.12861. Epub 2018 Nov 29.
2. Istituto Nazionale di Statistica (ISTAT). Previsioni della popolazione residente e delle famiglie. Popolazione in calo progressivo. 2022 Sep 22;1-31.
3. Bourne RRA, Steinmetz JD, Saylan M, Mersha AM, Weldemariam AH, Wondmeneh TG, et al. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study. Lancet Glob Health. 2021 Feb;**9**(2):e144-e160. doi:

10.1016/S2214-109X(20)30489-7. Epub 2020 Dec 1.
4. Sabanayagam C, Cheng CY. Global causes of vision loss in 2015: are we on track to achieve the Vision 2020 target? Lancet Glob Health. 2017 Dec;**5**(12):e1164-e1165. doi: 10.1016/S2214-109X(17)30412-6. Epub 2017 Oct 11.
5. Flaxman SR, Bourne RRA, Resnikoff S, Ackland P, Braithwaite T, Cicinelli MV, et al. Global causes of blindness and distance vision impairment 1990-2020: a systematic review and meta-analysis. Lancet Glob Health. 2017 Dec;**5**(12):e1221-e1234. doi: 10.1016/S2214-109-X(17)30393-5. Epub 2017 Oct 11.
6. Bonsaksen T, Brunes A, Heir T. Quality of life in people with visual impairment compared with the general population. J Public Health. 2023 Jul 8. doi:10.1007/s10389-023-01995-1.
7. Burton MJ, Ramke J, Marques AP, Bourne RRA, Congdon N, Jones I, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. Lancet Glob Health. 2021;**9**(4):e489-551. doi: 10.1016/S2214-109-X(20)30488-5. Epub 2021 Feb 16.
8. Nuzzi A, Becco A, Boschiroli A, Coletto A, Nuzzi R. Blindness and visual impairment: quality of life and accessibility in the city of Turin. Front Med. (Lausanne). 2024 Mar 21;**11**:1361631. doi: 10.3389/fmed.2024.1361631.
9. Società Oftalmologica Italiana (SOI). Glaucoma. L'importanza di una diagnosi precoce. Available from: https://www.sedesoi.com/vademecum-glaucoma/ [Last accessed: 2024 Nov 7].
10. Avogaro A, Fadini GP. Microvascular complications in diabetes: A growing concern for cardiologists. Int J Cardiol. 2019 Sep 15;**291**:29-35. doi: 10.1016/j.ijcard.2019.02.030. Epub 2019 Feb 25.
11. Bourne RRA, Jonas JB, Bron AM, Cicinelli MV, Das A, Flaxman SR, et al; Vision Loss Expert Group of the Global Burden of Disease Study. Prevalence and causes of vision loss in high-income countries and in Eastern and Central Europe in 2015: magnitude, temporal trends and projections. Br J Ophthalmol. 2018 May;**102**(5):575-585. doi: 10.1136/bjophthalmol-2017-311258. Epub 2018 Mar 15.
12. Vision Loss Expert Group of the Global Burden of Disease Study; GBD 2019 Blindness and Vision Impairment Collaborators. Global estimates on the number of people blind or visually impaired by glaucoma: A meta-analysis from 2000 to 2020. Eye (Lond). 2024 Aug;**38**(11):2036-2046. doi: 10.1038/s41433-024-02995-5. Epub 2024 Apr 2.
13. Associazione Medici Diabetologi (AMD) - Società Italiana di Diabetologia (SID). Standard italiani per la cura del diabete mellito. 2018; 6-12.
14. Li JQ, Welchowski T, Schmid M, Mauschitz MM, Holz FG, Finger RP. Prevalence and incidence of age-related macular degeneration in Europe: a systematic review and meta-analysis. Br J Ophthalmol. 2020 Aug;**104**(8):1077-1084. doi: 10.1136/bjophthalmol-2019-314422. Epub 2019 Nov 11.
15. Wittenborn JS, Zhang X, Feagan CW, Crouse WL, Shrestha S, Kemper AR, et al. The economic burden of vision loss and eye disorders among the United States population younger than 40 years. Ophthalmology. 2013 Sep;**120**(9):1728-35. doi: 10.1016/j.ophtha.2013.01.068. Epub 2013 Apr 28.
16. Albrecht M, Nica M, Colombo D, Ferri C, Tadini P, Introini U, et al. Il trattamento con farmaci intravitreali anti-VEGF in pazienti naïve in Italia. Global & Regional Health Technology Assessment. 2018;**5**:1-10. doi:10.1177/2284240318793905.
17. Bandello F, Augustin A, Sahel JA, Benhaddi H, Negrini C, Hieke K, et al. Association between visual acuity and medical and non-medical costs in patients with wet age-related macular degeneration in France, Germany and Italy. Drugs Aging. 2008;**25**(3):255-68. doi: 10.2165/00002512-200825030-00007.
18. Christensen TL, Poulsen PB, Holmstrom S, Walt JG, Vetrugno M. A Markov modelled pharmacoeconomic analysis of bimatoprost 0.03% in the treatment of glaucoma as an alternative to filtration surgery in Italy. Curr Med Res Opin. 2005 Nov;**21**(11):1837-44. doi: 10.1185/030079905X65592.
19. De Natale R, Le Pen C, Berdeaux G. Efficiency of glaucoma drug regulation in 5 European countries: a 1995-2006 longitudinal prescription analysis. J Glaucoma. 2011 Apr-May;**20**(4):234-9. doi: 10.1097/ijg.0b013e3181e0791c.
20. Denti C, Garattini L, Lanzetta P, Parazzini F, Ricci E, Gruppo di Studio Progetto CARMA. Costi della Degenerazione Maculare legata all'età in Italia. [Cost of Age-Related MAcular degeneration in Italy]. Pharmacoeconomics-Ital-Res-Articles. 2002 Sep;**4**(2):57-63. doi: 10.1007/BF03320595. Epub 2013 Feb 27.
21. Fea AM, Cattel F, Gandolfi S, Buseghin G, Furneri G, Costagliola C. Cost-utility analysis of trabecular microbypass stents (TBS) in patients with mild-to-moderate open-angle Glaucoma in Italy. BMC Health Serv Res. 2021 Aug 17;**21**(1):824. doi: 10.1186/s12913-021-06862-x.
22. Ferrario L, Foglia E, Garagiola E. Innovazione nel trattamento del glaucoma: sostenibilità dell'adozione del device XEN gel stent all 'interno del contesto italiano. 2020;**7**:1-40. doi: 10.25428/ucresearchreport/7_2020.
23. Foglia E, Ferrario L, Bandello F, Ferri C, Figini I, Franzin M, et al. Diabetic macular edema, innovative technologies and economic impact: New opportunities for the Lombardy Region healthcare system? Acta Ophthalmol. 2018 Jun;**96**(4):e468-e474. doi: 10.1111/aos.13620. Epub 2017 Dec 14.
24. Gandjour A, Kleinschmit F, Lauterbach KW; INTERCARE International Investigators. European comparison of costs and quality in the prevention of secondary complications in Type 2 diabetes mellitus (2000-2001). Diabet Med. 2002 Jul;**19**(7):594-601. doi: 10.1046/j.1464-5491.2002.00763.x.
25. Garattini L, Castelnuovo E, Lanzetta P, Viscarra C, Ricci E, Parazzini F, et al. Direct medical costs of age-related macular degeneration in Italian hospital ophthalmology departments. A multicenter, prospective 1-year study. Eur J Health Econ. 2004 Feb;**5**(1):22-7. doi: 10.1007/s10198-003-0198-x.
26. Holmstrom S, Buchholz P, Walt J, Wickstrøm J, Aagren M. The cost-effectiveness of bimatoprost, latanoprost and timolol in treatment of primary open angle glaucoma in five European countries. Curr Med Res Opin. 2006 May;**22**(5):897-905. doi: 10.1185/030079906X104687.

27. Hommer A, Wickstrøm J, Friis MM, Steeds C, Thygesen J, Ferreras A, et al. A cost-effectiveness analysis of fixed-combination therapies in patients with open-angle glaucoma: a European perspective. Curr Med Res Opin. 2008 Apr;**24**(4):1057-63. doi: 10.1185/030079908x280626. Epub 2008 Feb 29.
28. Invernizzi A, Bevilacqua MT, Cozzi M, Bianchi C, Pagani A, Cigada M, et al. Diabetic retinopathy screening: The first telemedical approach in an Italian hospital. Eur J Ophthalmol. 2016 Jun 10;**26**(4):369-74. doi: 10.5301/ejo.5000719. Epub 2015 Dec 14.
29. Koleva D, Motterlini N, Schiavone M, Garattini L; Study Group GLAUCO. Medical costs of glaucoma and ocular hypertension in Italian referral centres: a prospective study. Ophthalmologica. 2007;**221**(5):340-7. doi: 10.1159/000104765.
30. Lazzaro C, van Steen C, Ghirelli G, Sacchi M, Sisto D, Uva M, et al. A latanoprost cationic emulsion (STN1013001) vs. other latanoprost formulations (Latanoprost) in open angle glaucoma/ocular hypertension and ocular surface disease: an Italian cost-utility analysis. Expert Rev Pharmacoecon Outcomes Res. 2023 Feb;**23**(2):251-265. doi: 10.1080/14737167.2023.2161515. Epub 2023 Jan 9.
31. Lee PP, Kelly SP, Mills RP, Traverso CE, Walt JG, Doyle JJ, et al. Glaucoma in the United States and europe: predicting costs and surgical rates based upon stage of disease. J Glaucoma. 2007 Aug;**16**(5):471-8. doi: 10.1097/IJG.0b013e3180575202.
32. Muscio A, Ciriaci D, Cruciani F. A simulation of cost-benefit analysis of blindness prevention in Italy. Clin Ter. 2011;**162**(6):e187-94.
33. Perrone V, Dovizio M, Veronesi C, Citraro R, De Francesco A, Dell'Orco S, et al. Retrospective Analysis of the Pharmaco-Utilization of VEGF Inhibitors and Health Care Costs among Patients with Wet Age-Related Macular Degeneration and Other Ocular Diseases in Italy. Int J Environ Res Public Health. 2022 Feb 23;**19**(5):2548. doi: 10.3390/ijerph19052548.
34. Perrone V, Formica D, Piergentili B, Rossetti L, Degli Esposti L. Real-World Analysis on the Characteristics, Therapeutic Paths and Economic Burden for Patients Treated for Glaucoma in Italy. Healthcare (Basel). 2023 Feb 21;**11**(5):635. doi: 10.3390/healthcare11050635.
35. Porta M, Rizzitiello A, Tomalino M, Trento M, Passera P, Minonne A, et al. Comparison of the cost-effectiveness of three approaches to screening for and treating sight-threatening diabetic retinopathy. Diabetes Metab. 1999 Mar;**25**(1):44-53.
36. Scarpa G, Urban F, Vujosevic S, Tessarin M, Gallo G, Visentin A, et al. The Nonmydriatic Fundus Camera in Diabetic Retinopathy Screening: A Cost-Effective Study with Evaluation for Future Large-Scale Application. J Ophthalmol. 2016;2016:4625096. doi: 10.1155/2016/4625096. Epub 2016 Nov 3.
37. Scuteri D, Vero A, Zito M, Naturale MD, Bagetta G, Nucci C, et al. Diabetic retinopathy and age-related macular degeneration: a survey of pharmacoutilization and cost in Calabria, Italy. Neural Regen Res. 2019 Aug;**14**(8):1445-1448. doi: 10.4103/1673-5374.253528.
38. Traverso CE, Walt JG, Kelly SP, Hommer AH, Bron AM, Denis P, et al. Direct costs of glaucoma and severity of the disease: a multinational long term study of resource utilisation in Europe. Br J Ophthalmol. 2005 Oct;**89**(10):1245-9. doi: 10.1136/bjo.2005.067355.
39. Meier-Gibbons F, Töteberg-Harms M. Influence of Cost of Care and Adherence in Glaucoma Management: An Update. J Ophthalmol. 2020 Apr 8;**2020**:5901537. doi: 10.1155/2020/5901537.
40. Lazcano-Gomez G, Ramos-Cadena MLA, Torres-Tamayo M, Hernandez de Oteyza A, Turati-Acosta M, Jimenez-Román J. Cost of glaucoma treatment in a developing country over a 5-year period. Medicine (Baltimore). 2016 Nov;**95**(47):e5341. doi: 10.1097/MD.0000000000005341.
41. Wong WL, Su X, Li X, Cheung CM, Klein R, Cheng CY, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Glob Health. 2014 Feb;**2**(2):e106-16. doi: 10.1016/S2214-109X(13)70145-1. Epub 2014 Jan 3.
42. Burton MJ, Ramke J, Marques AP, Bourne RRA, Congdon N, Jones I, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. Lancet Glob Health. 2021 Apr;**9**(4):e489-e551. doi: 10.1016/S2214-109X(20)30488-5. Epub 2021 Feb 16.
43. Ministry of Health, Italy. Prevenzione ipovisione e cecità. Available from: https://www.salute.gov.it/portale/prevenzioneIpovisioneCecita/homePrevenzioneIpovisioneCecita.jsp [[Last accessed: 2024 Nov 7].
44. Law 10 February 1962, n. 66. Nuove disposizioni relative all'Opera nazionale per i ciechi civili. GU Serie Generale n. 61 del 07-03-1962. Available from: https://www.gazzettaufficiale.it/eli/id/1962/03/07/062U0066/sg [Last accessed: 2024 Nov 7].
45. Nuove norme in materia di indennità di accompagnamento ai ciechi civili ed ai pluriminorati. GU Serie Generale n.7 del 10-01-1992). Available from: https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1992-01-10&atto.codiceRedazionale=092G0014 [Last accessed: 2024 Nov 7].
46. Law 21 November 1988, n. 508. Norme integrative in materia di assistenza economica agli invalidi civili ai ciechi civili e ai sordomuti. GU Serie Generale n. 277 del 25-11-1988. Available from: https://www.gazzettaufficiale.it/eli/id/1988/11/25/088G0583/sg [Last accessed: 2024 Nov 7].
47. Ministry of Health, Italy. Relazione del ministro della Salute sullo stato di attuazione delle politiche inerenti la prevenzione della cecità, l'educazione e la riabilitazione visiva (legge 284/97) - Dati 2020. Available from: https://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?id=3402 [Last accessed: 2024 Nov 7].
48. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care. 2004 May;**27**(5):1047-53. doi:

10.2337/diacare.27.5.1047.
49. Associazione Medici Diabetologi (AMD), Associazione Medici Dirigenti (ANAAO-ASSOMED), Consorzio Mario Negri Sud, et al. Linee-guida per lo screening, la diagnostica e il trattamento della retinopatia diabetica in Italia. 2015.

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Supplementary table 1 - Full search strategy developed for each database.

Database	Search strategy	Number of retrieved records
PubMed/MEDLINE	(“Glaucoma”[MeSH Terms] OR “Retinal Diseases”[MeSH Terms] OR “Macular Degeneration”[MeSH Terms] OR “Glaucomas”[Title/Abstract] OR “Maculopathy”[Title/Abstract] OR “Maculopathies”[Title/Abstract] OR “Eye Diseases”[MeSH Terms] OR “Blindness”[Mesh] OR “Blindness”[Title/Abstract]) AND (“Cost of Illness”[MeSH Terms] OR “Health Care Costs”[MeSH Terms] OR “Health Expenditures”[MeSH Terms] OR “Direct Service Costs”[MeSH Terms] OR “Costs and Cost Analysis”[MeSH Terms] OR “Costs”[Title/Abstract] OR “Cost”[Title/Abstract]) AND (“Italy”[MeSH Terms] OR “Italy”[Title/Abstract])	77
Scopus	(TITLE-ABS-KEY(Glaucoma OR “Retinal Diseases” OR “Macular Degeneration” OR “Maculopathy” OR “Maculopathies” OR “Eye Diseases” OR “Blindness”)) AND (TITLE-ABS-KEY(cost OR costs)) AND (TITLE-ABS-KEY(Italy))	80
EMBASE	‘cost’/exp OR cost:ti OR cost:ab OR ‘cost benefit analysis’/exp OR ‘cost benefit analysis’:ti OR ‘cost benefit analysis’:ab OR ‘health care cost’/exp OR ‘health care cost’:ti OR ‘health care cost’:ab OR ‘health expenditure’/exp OR ‘health expenditure’:ti OR ‘health expenditure’:ab OR ‘health care cost’/exp OR ‘health care cost’:ti OR ‘health care cost’:ab OR ‘cost of illness’/exp OR ‘cost of illness’:ti OR ‘cost of illness’:ab AND ‘blindness’/exp OR blindness:ti OR blindness:ab OR ‘eye disease’/exp OR ‘eye disease’:ti OR ‘macular degeneration’/exp OR ‘macular degeneration’:ti OR’retina disease’/exp OR ‘retina disease’:ti OR ‘retina disease’:ab OR ‘glaucoma’/exp OR glaucoma:ti OR glaucoma:ab AND ‘italy’/exp OR italy:ti OR italy:ab	204

Supplementary table 2 - Eligibility criteria defined according to PEOS framework: Population (P), Exposure (E), Outcome (O), and Study design (S).

PECOS framework	Inclusion criteria
Population (P),	Subjects of any age affected by glaucoma, diabetic retinopathy, or macular degeneration
Exposure (E)	Any of the three conditions (glaucoma, diabetic retinopathy, and macular degeneration)
Outcome (O)	Healthcare costs (direct and indirect) of the disease
Study design (S)	Observational studies (cohort, case-control, cross-sectional), trials, and economic evaluations using simulation models or administrative databases
Language	English and Italian
Time filter	Last 20 years
	Exclusion criteria
Population (P),	Subjects not affected by glaucoma, diabetic retinopathy, or macular degeneration
Exposure (E)	Anything other than glaucoma, diabetic retinopathy, or macular degeneration
Outcome (O)	Anything not related to direct and indirect costs
Study design (S)	Not original (reviews with or without meta-analysis), not performed among humans, book, book chapter, thesis, no full-text papers (abstract, conference paper, letter, commentary, note)

Supplementary table 3a - ISPOR Good Research Practices assessment.

Study	ISPOR Domain	Assessment
De Natale et al.	Data Sources and Study Design	Partially Adequate
	Transparency of Data Handling	Partially Adequate
	Confounding and Bias Control	Partially Adequate
	Analytic Methods	Partially Adequate
	Contextual Relevance	Adequate

Supplementary table 3b - CHEERS checklist assessment.

Study	Title and Abstract	Background and Objectives	Target Population and Setting	Perspective of Analysis	Comparators	Time Horizon	Discount Rate	Sensitivity Analysis
Christensen et al.	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Fea et al.	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Ferrario et al.	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Foglia E et al	Adequate	Adequate	Adequate	Adequate	Partially Adequate	Partially Adequate	Adequate	Partially Adequate
Holmstrom S et al	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Hommer A et al	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Lazzaro C et al	Adequate	Adequate	Partially Adequate	Adequate	Partially Adequate	Partially Adequate	Partially Adequate	Adequate
Muscio A et al	Adequate	Adequate	Partially Adequate	Adequate	Adequate	Partially Adequate	Partially Adequate	Adequate

Supplementary table 4 - Approved medications and treatment protocols for Glaucoma, DR and AMD in the European Union.

Disease	Drug Name (Commercial Name)	Mode of Administration and Dosing	Duration of Use	Countries Approved	Usage Limitations (Age, Sex, Comorbidities)
Glaucoma	Bimatoprost (Lumigan)	Topical eye drops, 1 drop in the affected eye(s) once daily in the evening	Long-term	Approved in all EU countries	Not recommended for children under 18 years, caution in patients with a history of macular edema, iritis/uveitis, or aphakia
	Latanoprost (Xalatan)	Topical eye drops, 1 drop in the affected eye(s) once daily in the evening	Long-term	Approved in all EU countries	Not recommended for children under 18 years, caution in patients with severe asthma or in aphakic patients
	Travoprost (Travatan)	Topical eye drops, 1 drop in the affected eye(s) once daily in the evening	Long-term	Approved in all EU countries	Not recommended for children under 18 years, caution in patients with aphakia, pseudophakia with torn posterior lens capsule, or anterior chamber lenses
	Timolol (Timoptic)	Topical eye drops, 1 drop in the affected eye(s) twice daily	Long-term	Approved in all EU countries	Contraindicated in patients with bronchial asthma, severe COPD, sinus bradycardia, AV block, or overt heart failure
	Dorzolamide (Trusopt)	Topical eye drops, 1 drop in the affected eye(s) two to three times daily	Long-term	Approved in al EU countries	Contraindicated in patients with severe renal impairment, hyperchloremic acidosis; not recommended for children under 18 years
	Brinzolamide (Azopt)	Topical eye drops, 1 drop in the affected eye(s) twice daily	Long-term	Approved in all EU countries	Contraindicated in patients with severe renal impairment; not recommended for children under 18 years
	Brimonidine (Alphagan)	Topical eye drops, 1 drop in the affected eye(s) twice daily	Long-term	Approved in all EU countries	Contraindicated in children under 2 years; caution in patients with severe cardiovascular disease or depression
Diabetic etinopathy	Ranibizumab (Lucentis)	Intravitreal injection, 0.5 mg (0.05 mL) into the vitreous cavity once a month for three months, then as needed	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to ranibizumab
	Aflibercept (Eylea)	Intravitreal injection, 2 mg (0.05 mL) into the vitreous cavity once a month for five months, then every two months	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to aflibercept
	Bevacizumab (Avastin)	Intravitreal injection, 1.25 mg (0.05 mL) into the vitreous cavity as needed, typically once a month	Long-term	Approved for other indications in all EU countries, used off-label for DR	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to bevacizumab
	Dexamethasone implant (Ozurdex)	Intravitreal implant, 0.7 mg implant injected into the vitreous cavity, typically every 6 months or as needed	Long-term	Approved in all EU countries	Contraindicated in active ocular infections, advanced glaucoma, aphakia with ruptured posterior lens capsule, or hypersensitivity to dexamethasone
	Brolucizumab (Beovu)	Intravitreal injection, 6 mg (0.05 mL) into the vitreous cavity once a month for three months, then every 8-12 weeks	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to brolucizumab; caution in patients with a history of intraocular inflammation
	Faricimab (Vabysmo)	Intravitreal injection, 6 mg (0.05 mL) into the vitreous cavity every 4 weeks for the first 4 doses, then every 8-16 weeks depending on disease activity	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to faricimab

Age-Related Macular Degeneration	Ranibizumab (Lucentis)	Intravitreal injection, 0.5 mg (0.05 mL) into the vitreous cavity once a month, then as needed after three initial monthly doses	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to ranibizumab
	Aflibercept (Eylea)	Intravitreal injection, 2 mg (0.05 mL) into the vitreous cavity once a month for three months, then every two months	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to aflibercept
	Bevacizumab (Avastin)	Intravitreal injection, 1.25 mg (0.05 mL) into the vitreous cavity as needed, typically once a month	Long-term	Approved for other indications in all EU countries, used off-label for AMD	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to bevacizumab
	Verteporfin (Visudyne)	Intravenous injection followed by laser activation, typically one-time treatment, can be repeated if necessary	Short-term/ Long-term	Approved in all EU countries	Not recommended for patients with porphyria or severe hepatic impairment; avoid exposure to sunlight or bright indoor light for 48 hours after treatment
	Brolucizumab (Beovu)	Intravitreal injection, 6 mg (0.05 mL) into the vitreous cavity once a month for three months, then every 8-12 weeks	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to brolucizumab; caution in patients with a history of intraocular inflammation
	Faricimab (Vabysmo)	Intravitreal injection, 6 mg (0.05 mL) into the vitreous cavity every 4 weeks for the first 4 doses, then every 8-16 weeks depending on disease activity	Long-term	Approved in all EU countries	Contraindicated in ocular or periocular infections, active intraocular inflammation, known hypersensitivity to faricimab

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Prevalence of Rotavirus among Children in Baghdad, Iraq, detected by molecular methods

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Keywords: Rotavirus; children; molecular diagnosis; VP7 gene; Baghdad
Parole chiave: Rotavirus; bambini; diagnosi molecolare; gene VP7; Baghdad

Abstract

Background. *Rotavirus, a leading cause of severe gastroenteritis in young children, has a significant global impact due to its high prevalence and potential for causing severe dehydration.*
Study design. *This study was conducted to determine the prevalence of rotavirus among children under five years old in Baghdad, Iraq using molecular technique.*
Methods. *Between November 2022 and August 2023, 120 stool specimens were collected from children exhibiting symptoms of diarrhea at a pediatric hospital. Rotavirus infection was assessed using immunochromatographic test and reverse transcriptase-polymerase chain reaction to detect and characterize the VP7 gene, a key marker of rotavirus infection.*
Results. *It was observed that 97 out of 120 specimens tested positive for rotavirus, with immunochromatographic test detecting 110 cases (91.8%) and reverse transcriptase-polymerase chain reaction identifying 97 cases (80.8%) positive for the VP7 gene. The highest infection rates were observed in males (63.92%) and children aged 13-24 months (50.5%). Statistical analysis revealed an 80.8% overall prevalence of rotavirus among the study population.*
Conclusions. *These findings underscore the significant burden of rotavirus infection in Baghdad and highlight the effectiveness of reverse transcriptase-polymerase chain reaction in detecting rotavirus strains. The results align with previous studies in Iraq, emphasizing the need for continued surveillance and vaccination efforts to control rotavirus-related diarrhea and reduce its impact on young children in the region.*

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Introduction

Rotavirus is a double-stranded RNA (dsRNA) virus, non-enveloped, and classified into eight types (A-G) (1). Its genome consists of eleven dsRNA segments that encode six viral proteins (VP1–VP4, VP6, and VP7). Among these, VP4 and VP7 are responsible for viral attachment and neutralization of antigens (2). VP4 undergoes proteolytic cleavage at the tip of VP5, producing two fragments: VP8 and VP5. VP8 and VP6 form trimers that bind to VP5 in a circular arrangement, while VP7 and VP4 trimers attach to the VP8 and VP6 trimers on the outer shell (3).

The virus particle, a three-layered coated icosahedral particle, consists of two outer shell proteins i.e., VP4 (represents P genotypes) and VP7 (represents G-genotypes), one middle shell protein (VP6) and (VP2) is the innermost protein. Based on VP4 and VP7 variants, Rotavirus A is classified into 27 G- and 35 P- genotypes. The most significant Rotavirus types that commonly causes AGE are G2P-4, G4P-8, G1P-8, G3P-8, and G9P-8 (4).

Globally, the rotavirus strains G4P-8, G3P-8, G2P-4 G1P-8 and G9P-8 are recognized as the most significant sources of human infection, with G1P-8 being the most prevalent, accounting for 37.7% of cases (5-6).

Rotavirus A (RVA) is one of the most prevalent causes of diarrhea in infants and young children globally, particularly in severe cases that can lead to fatal dehydration. RVA from Group A is a leading cause of acute dehydrating diarrhea in humans. It exhibits wide genetic and antigenic diversity, with several human strains sharing similarities with RVA strains found in animals (7). Vaccinating a child with a serious infection is crucial because it provides active immunity once maternal antibodies wane, typically between four and six months of age. As of 2019, many countries have included this vaccine in their national immunization programs. Active immunity from vaccination is particularly important during the first few years of life, as the risk of severe infections, leading to hospitalization and death, is highest between 4 to 6 months. Rotavirus infection and replication occur in mature enterocytes and endocrine cells in the small intestine, specifically in non-dividing enterocytes located at the tips and middle of the villi. This suggests that certain factors expressed by these cell types are crucial for efficient viral replication and infection (8).

This study aimed to determine the prevalence of rotavirus infection among children in Baghdad City, Iraq, and to utilize molecular detection technique to identify and characterize the circulating rotavirus strains.

Materials and Methods

A cross sectional study was conducted at at a pediatric hospital and Baghdad teaching hospital. A total of 120 children presented acute diarrhea have been collected at time of study application during the period between November 2022 and August 2023. Information including age, sex, residence, type of feeding, and clinical features (diarrhea, fever, vomiting and degree of dehydration) were taken according to the WHO criteria. The objectives and methodology of this study were explained to all parents or guardians of the patients in the study to gain their verbal consent. All vaccinated children presented with acute diarrhea from the age of 6 months to the age of 5 years were included in this study,except for the following exclusions:

1. Infant younger than 6 months.
2. Children older than 5 years.
3. Hypersensitivity to (Rotarix®)vaccine.
4. Gastrointestinal Tract Congenital Malformation.
5. History of Intussusception.
6. Severe Combined Immunodeficiency Disease.

Collection of stool specimen

At a pediatric hospital in Baghdad City, 120 stool specimens were collected from young children with diarrhea between November 2022 and August 2023. All samples were collected and analyzed under aseptic conditions.

Sample preparation

In order to analyze the specimens, each of the frozen sample was totally thawed, then 1 g was weighed and diluted in 9 ml of phosphate buffer saline (1 : 10). Themixture was vortexed vigorously for 30 s followed by centrifugation at 5000 rpm for 10 min at room temperature. The supernatant was collected forthe molecular assay, samples were held in a clean Eppendorf tube andkept at −20°C until further.

Detection of rotavirus by immune chromategraphic test

Lumi Quick, Adeno-Rota Virus Antigen Comb Test Card Immuno Chromatography (IC)

This method is rapid for the qualitative detection of RV in stool samples. According to the company,

the chromatographic immunoassay was the first instrument for detecting Rotavirus in stool samples. The sample was added to a dilution buffer supplied by the kit and thoroughly mixed, then four drops were added to the sample well in the test cassette. The result was available after 5–10 min. Two bands should appear to indicate rotavirus positive; the control band and test band are visible. If only control band is visible, it is rotavirus negative. If control band is missing, the test is invalid. The sensitivity of the test was 98,9% and the specificity was 99,6% (9). (LumiQuickAdeno-RotaVirus Antigen Comb Test, Netherlands).

Detection of rotavirus by reverse transcriptase-polymerase chain reaction

Rotavirus was also detected from stool specimens using the RT-PCR). Stool supernatant samples were processed using FavroPrep™ to isolate viral nucleic acid. Viral RNA was isolated using a micro-spin column with a silica matrix following the manufacturer's instructions. For cDNA synthesis, the BioneerAccupower® RocketScript™ RT PreMix was used. This comprehensive system included all necessary reagents for efficient first-strand cDNA synthesis from RNA templates, provided in an easy-to-use, lyophilized, single-tube format. The RTase, an RNA-dependent DNA polymerase, was employed for the synthesis of cDNA.To ensure comprehensive coverage of all RNA sequences, random hexamer primers were used during the cDNA synthesis process. The resulting first-strand cDNA was used directly for polymerase chain reaction (PCR).

Specimens and reagents were maintained at room temperature. Ten microliters of RNA were added to the reaction tube, and 20 microliters of RNase-free water were added to achieve the total volume. The materials and reaction mixture were warmed to room temperature before starting the reaction. The mixture was gently mixed and centrifuged, and then the heat cycler was set up with the reaction tube.This process generated a pool of cDNA with varying lengths. For VP7 gene amplification via PCR, the components of the master mix were brought to room temperature before use, and the PCR master mix was prepared in a separate biohazard safety cabinet. To each pre-mixed, ready-to-use PCR reaction tube, which contained Taq DNA polymerase, dNTPs, $MgCl_2$, and reaction buffers from Bioneer (Korea), 3 µL of the forward primer (GGCTTTAAAAGAGAGAATTTCCGTCTGG) at 10 pmol/µL and 3 µL of the reverse primer (GGTCACATCATACAATTCT) at 10 pmol/µL were added. After thorough mixing of the reaction components using a micro centrifuge (10).

Ethical approval

Ethical approval for conducting this study was obtained from the College of Medicine, University of Baghdad, Iraq (**Ref.no. of Ethical approval (0211A) on the date 16-7-2023**).

Statistical analysis

The Statistical Packages of Social Sciences-SPSS (2019) program was used to detect the effect of difference groups factors in study parameters. Chi-square test was used to significant compare between percentage (0.05 and 0.01 probability) in this study (11).

Results

The results indicated that 97 out of 120 specimens tested positive for rotavirus infection in children with diarrhea, as shown in Tables 1 and 2. The ICT detected rotavirus in 110 cases (91.8%), while the RT-PCR test identified positive results for the VP7 gene in 97 cases (80.8%) of children under five years. The P- values statistically highly significant, and percentage of concordance among the two methods are non significant.

All positive specimens were further analyzed using RT-PCR to detect the VP7 gene, which is 1,062 bp in length. Primers specific to the VP7 gene were used to amplify the isolated RNA after the conversion to cDNA. Figure 1 shown the amplicon size of the VP7 gene at 1,062 bp.

Table 1 - Demographic characteristics of the participants/ Distribution according to Sex and Age groups

Factors		No (%)	P-value
Sex	Male	47 (39.1)	0.0027 **
	Female	73 (60.8)	
	Total	120 (100.0)	--
Age (year)	Age groups	No (%)	P-value
	1-12	51 (42.50%)	
	13-24	64 (53.33%)	0.0001 **
	25-48	3 (2.50%)	
	49-60	2 (1.67%)	
	Total	120 (100.0)	--

** (P≤0.01).

Table 2 - Comparing the results of the immunochromatographic test (ICT) and reverse transcriptase-polymerase chain reaction (RT-PCR) to detect rotavirus.

Method	Positive cases No (%)	Negative cases No (%)	P-value	Total No (%)
ICT	110 (91.67%)	10 (8.33%)	0.0001 **	120 (100%)
RT-PCR	97 (80.83%)	23 (19.17%)	0.0001 **	120 (100%)
P-value	0.366 NS	0.024 *	--	---

* (P≤0.05), ** (P≤0.01).

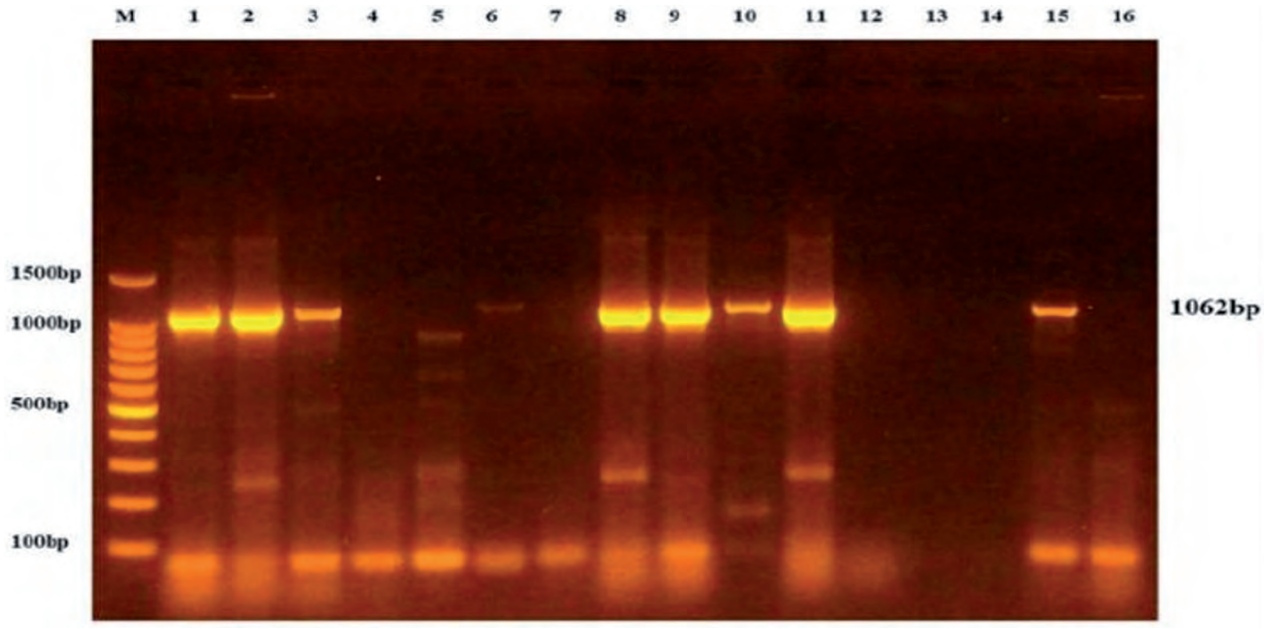

Figure 1 - Agarose gel electropherogramofreverse transcriptase-polymerase chain reaction (RT-PCR)-amplified fragment of VP7 gene of rotavirus from human.M: 100 bp DNA ladder; 1-16: Target fragment size: 1062bp.

The highest number of infected children was observed among males, with 62 cases (63.92%), compared to 35 cases (36.08%) in females. The age groups most affected were 13-24 months and 1-12 months, with 49 (50.5%) and 43 (44.3%) cases, respectively. The overall infection rate in Baghdad children under five years old was 80.8%, as shown in Tables 3 and 4. The P- values is highly significant.

Table 3 - Prevalence of human rotavirus detected by reverse transcriptase-polymerase chain reaction in Baghdad City according to

Sex	Positive cases (No (%)	Negative cases (No (%)
Female	35 (36.08%)	12 (52.17%)
Male	62 (63.92%)	11 (47.83%)
Total	97 (100%)	23 (100%)
P-value	0.0061 **	0.834 NS

** (P≤0.01).

Discussion

Rotaviruses are the leading cause of pediatric gastroenteritis globally, primarily affecting children under five years of age (2). Despite the assumption that improvements in infection control could reduce diarrheal deaths (12), there remains a significant

Table 4 - Prevalence of human rotavirus detected by reverse transcriptase-polymerase chain reaction in Baghdad City according to age group

Age stage (Month)	No. of positive cases No (%)	No. of negative cases No (%)
1-12	43 (44.3%)	8 (34.8%)
13-24	49 (50.5%)	15 (65.2%)
25-48	3 (3.1%)	0 (0%)
49-60	2 (2.1%)	0 (0%)
Total	97 (100%)	23 (100%)
P-value	0.0001 **	0.0001 **

** (P≤0.01).

risk of diarrheal disease.Rotavirus prevalence in human fecal specimens was determined using the immunochromatographictest. According to research (13), most cases of diarrhea among children under five in Iraq have been associated with rotavirus, as identified in previous studies. Based on rapid ICT results for rotavirus infection in stool specimens, 110 children in Baghdad City were positive (Table 3).These findings align with our study, where stool specimens were collected from 16 participants across five different Iraqi regions (Babil, Karbala, Missan, Qadissiya, and Wasit), showing comparable frequency and positive results using the ICT. Additionally, a study conducted on hospitalized children in Basrah, Iraq, using ICT, a simple and low-tech method with minimal equipment requirements, revealed a lower incidence of rotavirus infections (14).

Polymerase chain reaction analysis of human stool specimens was used to determine rotavirus prevalence. The PCR method is essential for identifying genes in various strains and avoids issues with primers that may not bind correctly to the template. In this study, the VP7 gene (glycoprotein) was identified due to its role in rotavirus pathogenesis and infection, serving as an outer capsid protein involved in neutralizing antibodies and facilitating entry into host cells (15). However, Isihak (2020) (16) demonstrated that RT-PCR was less effective for amplification compared to RT-qPCR when evaluating positive and negative controls. Thus, a more sensitive technique like RT-qPCR is recommended for improved PCR assay accuracy. Genotype specificity can effectively predict the origin of rotavirus strains in different host species. However, the situation is more complex, as various host species may exhibit diverse genotypes, and new or existing related host species could potentially release distinct rotavirus strains due to recognized genomic diversity across different hosts (17). Reverse transcription-PCR has been employed to identify common and uncommon VP7 (glycoprotein, G-genotype) proteins globally. The technique detected rotavirus in 80.8% of human samples (Table 3).

In contrast, a study in Iraqi Kurdistan found that only 37% of children with gastroenteritis were affected by rotavirus infection (18). This study indicated no statistically significant differences based on geographic location, gender, medical characteristics, type of therapy, or illness progression, except for the time of onset. Similarly, approximately 47.4% of acute gastroenteritis cases in diarrhea specimens showed no significant demographic differences between rotavirus and other causes of gastroenteritis, except for a higher prevalence in males. Clinical characteristics and disease progression were similar across these cases, with time of onset being the only notable exception. Among the infected children, 43 were in the 1–12-month age group, representing a 44.3% infection rate, while 49 were in the 13–24-month age group, representing a 50.5% infection rate. These findings are consistent with a study conducted in Ramadi City, Iraq (19).

Conclusion

The study's findings indicated that rotavirus infection is increasingly common among children in Baghdad, with a higher risk observed in younger children, particularly males. The RT-PCR andthe rapid ICT both showed a correlation, with RT-PCR demonstrating greater sensitivity compared to the rapid ICT.

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Author Contribution Statement: Maryam Kareem Ali (MA) and Jaafar Sataar Shia (JS) contributed equally to the experimental work and analysis of the data.

Conflict of interest: The authors declare that they have no competing interests.

Riassunto

Prevalenza di Rotavirus tra i bambini a Baghdad, Iraq, rilevata con metodi molecolari

Premesse. Il Rotavirus, uno dei principali agenti di gastroenterite grave nei bambini piccoli, ha un impatto globale significativo a causa della sua elevata prevalenza e della caratteristica di causare grave disidratazione.

Progetto dello studio. Questo studio è stato condotto per determinare la prevalenza di Rotavirus tra i bambini di età inferiore ai cinque anni a Baghdad, Iraq, utilizzando tecniche molecolari.

Metodi. Tra novembre 2022 e agosto 2023, sono stati raccolti 120 campioni di feci da bambini che presentavano sintomi di diarrea in un ospedale pediatrico. L'infezione da Rotavirus è stata misurata utilizzando il test immunocromatografico e la reazione a catena della polimerasi con trascrittasi inversa per rilevare e caratterizzare il gene VP7, un marcatore chiave dell'infezione da Rotavirus.

Risultati. 97 campioni su 120 sono risultati positivi al Rotavirus, con i test immunocromatografico che ha rilevato 110 casi (91,8%) e la reazione a catena della polimerasi con trascrittasi inversa che ha identificato 97 casi (80,8%) positivi per il gene VP7. I tassi di infezirone più elevati sono stati osservati nei maschi (63,92%) e nei bambini di età compresa tra 13 e 24 mesi (50,5%). L'analisi statistica ha rivelato una prevalenza complessiva di Rotavirus dell'80,8% nella

popolazione dello studio.

Conclusioni. Questi risultati sottolineano il peso significativo dell'infezione da Rotavirus a Baghdad e mettono in evidenza l'efficacia della reazione a catena della polimerasi con trascrittasi inversa nel rilevamento dei ceppi di Rotavirus. I risultati sono in linea con studi precedenti in Iraq, sottolineando la necessità di una sorveglianza continua e di sforzi di vaccinazione per controllare la diarrea correlata al Rotavirus e ridurne l'impatto sui bambini piccoli nella regione.

References

1. Matthijnssens J, Van Ranst M. Genotype constellation and evolution of group A rotaviruses infecting humans. Curr OpinVirol. 2012 Aug;**2**(4):426-33. doi: 10.1016/j.coviro.2012.04.007. Epub 2012 Jun 9. PMID: 22683209.
2. LeClair CE, McConnell KA. Rotavirus. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. PMID: 32644377.
3. Settembre EC, Chen JZ, Dormitzer PR, Grigorieff N, Harrison SC. Atomic model of an infectious rotavirus particle. EMBO J. 2011 Jan 19;**30**(2):408-16. doi: 10.1038/emboj.2010.322. Epub 2010 Dec 14. PMID: 21157433.
4. Matthijnssens J, Ciarlet M, Rahman M, Attoui H, Bányai K, Estes MK, et al. Recommendations for the classification of group A rotaviruses using all 11 genomic RNA segments. Arch Virol. 2008;**153**(8):1621-9. doi: 10.1007/s00705-008-0155-1. Epub 2008 Jul 5. PMID: 18604469; PMCID: PMC2556306.
5. Bányai K, László B, Duque J, Steele AD, Nelson EA, Gentsch JR, et al. A systematic review of regional and temporal trends in global rotavirus strain diversity in the pre-rotavirus vaccine era: insights for understanding the impact of rotavirus vaccination programs. Vaccine. 2012 Apr 27;**30** Suppl 1:A122-30. doi: 10.1016/j.vaccine.2011.09.111. PMID: 22520121.
6. Dóró R, Farkas SL, Martella V, Bányai K. Zoonotic transmission of rotavirus: surveillance and control. Expert Rev Anti Infect Ther. 2015;**13**(11):1337-50. doi: 10.1586/14787210.2015.1089171. Epub 2015 Oct 1. PMID: 26428261.
7. Lundgren O, Svensson L. Pathogenesis of rotavirus diarrhea. Microbes Infect. 2001 Nov 7;**3**(13):1145-1156. doi: 10.1016/S1286-4579(01)01475-7. PMID: 11709295.
8. Gouvea V, Glass RI, Woods P, Taniguchi K, Clark HF, Forrester B, et al. Polymerase chain reaction amplification and typing of rotavirus nucleic acid from stool specimens. J Clin Microbiol. 1990 Feb;**28**(2):276-82. doi: 10.1128/jcm.28.2.276-282.1990. PMID: 2155916.
9. Mijatovic-Rustempasic S, Tam KI, Kerin TK, Lewis JM, Gautam R, Quaye O, et al. Sensitive and specific quantitative detection of rotavirus A by one-step real-time reverse transcription-PCR assay without antecedent double-stranded-RNA denaturation. J Clin Microbiol. 2013 Sep;**51**(9):3047-54. doi: 10.1128/JCM.01192-13. Epub 2013 Jul 12. PMID: 23850952; PMCID: PMC3754639.
10. Chouikha A, Fodha I, Ben Hadj Fredj M, Ardhaoui M, Teleb N, Brini I, et al. Relationship between electropherotypes and VP7/VP4 genotypes of groupA rotaviruses detected between 2000 and 2007 in Tunisian children. Pathol Biol (Paris). 2011 Jun;**59**(3):e43-8. doi: 10.1016/j.patbio.2009.04.008. Epub 2009 May 29. PMID: 19481882.
11. Darren G, Mallery P. Statistical Packages of Social Sciences-SPSS/ IBM Statistics 26 step by step. 16th ed. New York: Taylor & Francis; 2019. https://doi.org/10.4324/9780429056765.
12. Mutlak QM, Abdulridha MK, Al-Huseini LMA. Updates in the prevalence of rotavirus gastroenteritis in Babylon City. Al Mustansiriyah J Pharm Sci. 2018;**18**(2):1-12. https://doi.org/10.32947/ajps.v18i2.479.
13. Fenjan MN, Jarullah BA. Molecular identification and phylogenetic analysis of rotavirus in children suffering from diarrhea under five years old in Thi-Qar Province. Iraqi J Edu Pure Sci 2019;**9**(1):82-91. http://doi.org/10.32792/utq.jceps.09.01.09.
14. Aldawmy FK, Thwiny HT, AboAlmaali HM. Epidemiological and molecular study of Rotavirus infection among humans and animals in Karbala and Basrah provinces. Iraqi J Vet Sci. 2021Apr; **35**(2):403-410. https://doi.org/10.33899/ijvs.2020.126997.1428.
15. Trask SD, McDonald SM, Patton JT. Structural insights into the coupling of virion assembly and rotavirus replication. Nat Rev Microbiol. 2012 Jan 23;**10**(3):165-77. doi: 10.1038/nrmicro2673. PMID: 22266782; PMCID: PMC3771686.
16. Isihak FA. Diagnosis of reovirus infection in broiler breeder's flocks by using PCR technique in Erbil province. Iraqi J Vet Sci. 2020;**34**(1):77-81.Available from: https://www.vetmedmosul.com/article_164199_a1c33a81fcb81-b3ee6efaf9f2b976123.pdf
17. Afrad MH, Matthijnssens J, Moni S, Kabir F, Ashrafi A, Rahman MZ, et al. Genetic characterization of a rare bovine-like human VP4 mono-reassortantG6P-8 rotavirus strain detected from an infant in Bangladesh. Infect Genet Evol. 2013 Oct;**19**:120-6. doi: 10.1016/j.meegid.2013.06.030. Epub 2013 Jul 10. PMID: 23851022.
18. Mehdi SG, Niazi AD, Alhamdani FG. Burden of rotavirus gastroenteritis among under five years children at Al-AlwaiyaPaediatric Hospital. Iraqi Postgrad Med J. 2008;**7**(4):318-321. Available from: Microsoft Word - 10 (iasj.net).
19. Alani QA, Ai-Rawi SA, Salih AK, Al-Mawla SOG. Common Rota virus gastroenteritis in children under 5 years in Maternity and Children Teaching Hospital, Western Iraq. Anb Med J. 2012;**10**(1):1-7. Available from: https://amj.uoanbar.edu.iq/article_54060_5a5fe8c8c1a206086fed1e8f2a74cfa7.pdf.

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LETTER TO THE EDITOR

Experience of Safety and Health Promotion in Dolomites Area

Esperienza di promozione della salute e della sicurezza in area dolomitica

Keywords: Public health; alpine refuge; Prevention Department; health promotion; hygienic condition

Abstract

The mountain context represents a suitable setting for promoting health. In view of the Olympic Games, which are expected to take place in the Dolomites area in 2026, the outdoor Alpine environment must continue to meet all the health and safety requirements. Our recent experience, implemented in this area since summer 2024 through the Prevention Department of the Local Health Authority ULSS 1 Dolomiti, aims to encourage multi-sector preventive public health policies, in order to improve the "Shelters" ("rifugi", in Italian) hygiene, to strengthen the safety requirements, and to implement preventive projects.

Sir:

The Belluno province is predominantly mountainous, consisting of rugged mountains crossed by deep, narrow valleys. Public Health challenges are particularly demanding in this territory, being characterized by large territorial extension, low population density, geomorphological features not easy in some local areas. Therefore, the offer of initiatives proposed both for the population and for businesses operating in this area must be as widespread and targeted as possible. This geographical context is also highly suited to tourism (1,2). Since 2009, the United Nations Educational, Scientific, and Cultural Organization—UNESCO—proclaimed the Dolomites as a "World Heritage Site", a natural asset with unique characteristics from a landscape, geology, geomorphology and anthropology viewpoints (3).

Starting from summer 2024, the Local Health Authority ULSS 1 Dolomiti introduced the "Healthy and Safe Refuge", a project aiming to improve the overall quality of the hygienic requirements, safety, and refuges' ability to promote health. In addition to the basic technical and hygienic–sanitary prerequisites legally required (4), to be defined as "healthy and safe", the refuge must enhance the hygienic–sanitary suitability and the health safety, also in collaboration with the Emergency Medical Service – SUEM 118; furthermore, this project is oriented towards health promotion. The involvement of the Association of Alpine Refuge Managers of Veneto Region – AGRAV, and the Italian Alpine Club – CAI, was fundamental to obtaining a good response from the structures for the purposes of joining this project. All requirements declared, in particular those with a direct impact on human health, were evaluated by the Healthcare Workers of the Prevention Department through a dedicated checklist. Moreover, for the purposes of overall monitoring, the application for joining this project must be accompanied by the most recent analytical test report relating to the water intended for human consumption. The main critical issues concerned the microbial water

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quality: in 3 out of 27 cases (11.1%), attributable to mountain facilities that did not benefit from public water supply, non-compliances were detected, due to the presence of indicators of slight contamination by Enterobacteriaceae: the immediate corrective actions, which allowed the resolution of all the criticalities, provided for the cleaning of the water tanks and the adoption of a hypochlorite chlorination system, directly managed by the refuge manager after appropriate training (5-7). To date, all 27 refuges joining the project (25% of the mountain facilities potentially eligible for the enrollment in the Dolomites area) benefited from the recognition, having met, at the end of the improvement process, all the requirements.

Targeted territorial public health policies should be oriented to guarantee the minimal requirements in this particular type of buildings, and to improve health promotion projects in an area intrinsically favorable to easily adopt correct healthy choices, including walking and hiking, as well as the incentive to wear appropriate clothing and to use protective sun creams to prevent sunburn and skin melanoma. Therefore, the institutional commitment must lean both towards facilitating the full recruitment of shelters in the provincial area covered by the project and the extension at the regional level and in the territories of neighboring regions. Furthermore, project paths aimed at measuring blood pressure at altitude and supplying telemedicine backpacks have already been initially developed in this setting.

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References

1. Regional statistical system of the Veneto Region. Available from: https://statistica.regione.veneto.it/banche_dati_economia_turismo.jsp [Last accessed: 2024 Nov 25].
2. Caravaggi L, Imbroglini C. La montagna resiliente. Scienze del Territorio 2016 Nov 28;**4**:145-152. https://doi.org/10.13128/Scienze_Territorio-19400.
3. United Nations Educational, Scientific and Cultural Organization (UNESCO). Dolomites. Available from: https://www.unesco.it/it/unesco-vicino-a-te/siti-patrimonio-mondiale/dolomiti [Last accessed: 2024 Nov 25].
4. Resolution of the Veneto Regional Council n. 109 of 5 February 2019. Alpine refuge requirements. Available from: https://bur.regione.veneto.it/BurvServices/pubblica/DettaglioDgr.aspx?id=387851 [Last accessed: 2024 Nov 25].
5. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. Available from: https://eur-lex.europa.eu/eli/dir/2020/2184/oj [Last accessed: 2024 Nov 25].
6. Italian Legislative Decree 23 February 2023, n. 18. Fulfillment of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. Available from: https://www.fao.org/faolex/results/details/en/c/LEX-FAOC224845 [Last accessed: 2024 Nov 25].
7. Veneto Region. Decree n. 15 of 9 February 2009 of the Manager of the Animal Health and Food Hygiene Project Unit. Available from: https://bur.regione.veneto.it/BurvServices/pubblica/DettaglioDecreto.aspx?id=214662 [Last accessed: 2024 Nov 25].

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