ISSN: 2785-7263 DOI: 10.54103/dn/32755

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PROTOCOL

INDEPENDENCE - Impact Of Nursing Diagnoses EPidemiology iN aDdiction and mENtal health serviCEs: a prospective study protocol

Claudia Fantuzzi[1,2,3], Valentina Zeffiro[1], Cristina Brandolin[2], Gianfranco Sanson[3]

[1] Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy
[2] Department of Mental Health and Addictions, Azienda Sanitaria Universitaria Giuliano Isontina (ASUGI), Trieste, Italy
[3] Department of Medical, Surgical and Health Sciences, University of Trieste, Trieste, Italy

Findings:

The INDEPENDENCE protocol describes a prospective cohort study in community mental health and addiction services in Trieste, targeting at least 116 participants over six months. NANDA-I nursing diagnoses will be assessed at baseline, three and six months. Analyses will examine diagnostic prevalence, distribution, persistence, resolution, and associations with clinical, sociodemographic and care-related outcomes.

ABSTRACT

BACKGROUND: Mental health and substance use disorders are associated with complex care needs that often extend beyond psychiatric diagnoses. Nursing diagnoses (NDs) provide a standardized framework to describe human responses to health conditions and may improve the representation of patient complexity. However, evidence regarding NDs' epidemiology and longitudinal evolution in community mental health and addiction services remains limited.

AIM: The INDEPENDENCE study will aim to describe the epidemiological profile of NDs among individuals receiving care from community mental health and/or addiction services.

METHODS: INDEPENDENCE will have a prospective longitudinal cohort study design. All adults consecutively admitted in community mental health and addiction services in Trieste (Italy) will be followed for six months. NDs will be assigned according to the NANDA-I taxonomy following structured nursing assessment and agreement between at least two trained nurses. Assessments will be performed at enrollment and repeated after three and six months. The primary outcome will be the epidemiological characterization of NDs at admission (frequency, number and distribution). The changes in NDs prevalence and distribution over time and the clinical, sociodemographic, and organizational predictors of NDs persistence or resolution will be explored as secondary outcomes. Descriptive statistics and multivariable regression models will be used.

CONCLUSIONS: The study will provide longitudinal evidence on NDs in mental health and addiction services and may support implementation of standardized nursing languages, nursing workforce planning, and service development.

ETHICS: The protocol was approved by the Regional Ethics Committee of Friuli Venezia Giulia (Prot. 0050044/P/GEN/ARCS dated December 19, 2025)

KEYWORDS: *Nursing diagnosis, Mental health, Substance use disorder, Observational study*

Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it*, Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

Milano University Press

Submission received: 09/09/2026
End of Peer Review process: 21/09/2026
Accepted: 22/09/2026

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ISSN: 2785-7263 DOI: 10.54103/dn/32755

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PROTOCOLLO

INDEPENDENCE Impatto dell'epidemiologia delle diagnosi infermieristiche nei servizi per le dipendenze e la salute mentale: protocollo di uno studio prospettico

Claudia Fantuzzi[1,2,3], Valentina Zeffiro[1], Cristina Brandolin[2], Gianfranco Sanson[3]

[1] Dipartimento di Biomedicina e Prevenzione, Università degli Studi di Roma Tor Vergata, Roma, Italia
[2] Dipartimento di Salute Mentale e Dipendenze, Azienda Sanitaria Universitaria Giuliano Isontina (ASUGI), Trieste, Italia
[3] Dipartimento di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Trieste, Italia

Riscontri:

Il protocollo INDEPENDENCE prevede uno studio di coorte prospettico nei servizi territoriali di salute mentale e dipendenze di Trieste, con almeno 116 partecipanti e un follow-up di sei mesi. Le diagnosi infermieristiche NANDA-I saranno rilevate all'arruolamento, a tre e sei mesi. Verranno analizzate prevalenza, distribuzione, persistenza e risoluzione delle diagnosi, nonché le associazioni con caratteristiche cliniche, sociodemografiche ed esiti assistenziali.

ABSTRACT

BACKGROUND: I disturbi di salute mentale e da uso di sostanze sono associati a bisogni assistenziali complessi che travalicano la mera diagnosi psichiatrica. Le diagnosi infermieristiche (DI) consentono di descrivere in modo standardizzato le risposte umane alle condizioni di salute e possono migliorare la rappresentazione della complessità assistenziale. Tuttavia, le evidenze sul loro impiego nei servizi di salute mentale e dipendenze rimangono limitate.
OBIETTIVO: Lo studio INDEPENDENCE vuole descrivere il profilo epidemiologico delle DI tra gli utenti in carico ai servizi di salute mentale e dipendenze.
METODI: Verrà condotto uno studio di coorte prospettico longitudinale. Tutti gli adulti consecutivamente presi in carico nei sevizi di salute mentale e dipendenze italiani saranno seguiti per sei mesi. Le DI saranno formulate secondo la tassonomia NANDA-I mediante accertamento infermieristico strutturato e accordo tra almeno due infermieri formati. Le valutazioni saranno effettuate al primo contatto e ripetute dopo tre e sei mesi. L'epidemiologia delle DI alla presa in carico (frequenza, numero e distribuzione) rappresenta l'outcome primario. Variazioni nella prevalenza e distribuzione nel tempo delle DI e predittori clinici, sociodemografici e organizzativi della loro persistenza o risoluzione saranno considerati outcome secondari. I dati saranno analizzati mediante statistica descrittiva e modelli di regressione multivariata.
CONCLUSIONI: Lo studio fornirà evidenze longitudinali sulle DI nei servizi per la salute mentale e le dipendenze e potrà quindi supportare la loro implementazione per la pianificazione delle risorse infermieristiche necessarie e lo sviluppo dei servizi.
CONSIDERAZIONI ETICHE: protocollo approvato dal Comitato Etico Regionale del Friuli-Venezia-Giulia (Prot. 0050044/P/GEN/ARCS del 19/12/2025).

KEYWORDS: *Diagnosi infermieristiche, Salute mentale, Disturbo da abuso di sostanze, Studio osservazionale*

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BACKGROUND

Mental health and substance use disorders represent a major global public health challenge and are among the leading causes of disability worldwide [1,2]. Community mental health and addiction services increasingly care for individuals presenting complex combinations of psychiatric symptoms, physical health conditions, social vulnerability, impaired functioning, and long-term support needs [2,3]. The multidimensional nature of these care needs requires a comprehensive assessment approach that extends beyond the identification of psychiatric diagnoses alone [3,4]. Although nurses constitute the largest healthcare workforce worldwide, their contribution to patient care remains only partially represented within healthcare information systems [5,6]. These have traditionally focused on medical diagnoses, procedures, and treatments, whereas nursing assessments, nursing diagnoses (NDs), interventions, and patient responses are often incompletely represented in structured data systems. As a consequence, the specific contribution of nursing care to patient outcomes, healthcare resource utilization, and service planning remains difficult to quantify, particularly because nursing data are not systematically captured within health information systems [5,7]. Standardized nursing languages have been developed to address this limitation by providing structured representations of nursing knowledge, clinical reasoning, and patient responses that can be integrated into electronic health records and patients' documentation [7–9]. Among standardized nursing terminologies, NANDA-I represents one of the most widely used and continuously updated classifications of NDs in clinical practice, education, and research [10,11]. NDs support the identification of human responses to health conditions and life processes, facilitate communication among professionals, and guide the selection of individualized nursing interventions [11,12]. Growing evidence suggests that NDs can also provide clinically meaningful information regarding patient complexity and healthcare outcomes; moreover, studies conducted in different care settings have demonstrated that the number and type of nursing diagnoses are associated with indicators such as length of stay, nursing workload, and mortality, supporting the usefulness of nursing diagnostic data beyond routine documentation purposes [10,12–19].

The relevance of NDs may be particularly pronounced in mental health and addiction services, where care extends far beyond symptom monitoring and medication administration [3,4]. Nurses working in these settings routinely assess coping capacity, resilience, interpersonal relationships, role performance, sleep patterns, self-management abilities, risk behavior, and social participation. Many of these dimensions influence recovery trajectories and quality of life but are not adequately represented by psychiatric classifications such as the DSM taxonomy [4,20–22].

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Milano University Press

DISSERTATION NURSING V.6, N.1, (31/01/2027)

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Study rationale

Despite this potential relevance, evidence regarding the epidemiology of nursing diagnoses in mental health and addiction services remains limited [4,20]. Most available studies have been conducted in psychiatric inpatient units and have primarily focused on cross-sectional descriptions of NDs [23–25]. Community-based mental health services have received considerably less attention, and longitudinal evidence remains scarce [4,26,27]. Consequently, little is known about the evolution of NDs over time, the factors associated with their persistence or resolution, and their relationship with relevant clinical or organizational outcomes [12,28]. Furthermore, the prevalence, distribution, longitudinal trajectory, and prognostic significance of NDs in mental health and addiction real-world community services remain largely unexplored [4,20]. The generation of epidemiological evidence regarding NDs may contribute to improving the visibility of nursing care, supporting workforce planning, refining descriptions of patient complexity, and strengthening nursing-sensitive outcome research [5,10,28].

Aim and objectives

The INDEPENDENCE (Impact of Nursing Diagnoses EPidEmiology iN aDdiction and mENtal health serviCEs) study aims to describe the epidemiological profile of NDs among individuals receiving care from community mental health and/or addiction services. Secondary objectives are as follows: (1) to analyze the distribution of NDs according to clinical and sociodemographic characteristics; (2) to identify predictors of NDs resolution over a 6-month follow-up period; (3) to investigate the association between the number and type of NDs and relevant clinical and organizational outcomes.

METHODS

Design

INDEPENDENCE will be a prospective longitudinal cohort study designed to investigate the epidemiology and longitudinal evolution of NDs among individuals receiving care within community mental health and addiction services. Participants will be assessed at enrollment and subsequently followed through planned reassessments at three and six months. The results will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [29].

Setting

The study will be conducted within the Department of Mental Health and Addiction Services of Trieste, Italy. These services provide multidisciplinary community-based care to individuals with mental health disorders and/or substance use disorders.

Participants

All individuals consecutively admitted to the participating services during the recruitment period, to which a new clinical record will be assigned, will be considered for inclusion.

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Inclusion and exclusion criteria

Participants will be eligible if they: (1) are aged 18 years or older; (2) provide written informed consent for participation and authorize the use of their clinical data for research purposes.

Participants will be excluded if they: (1) refuse the baseline routine nursing assessment; (2) do not receive any nursing care (managed exclusively by other professionals such as psychiatrists or psychologists).

Sample size

Because the primary objective is epidemiological and recruitment will remain open throughout the study period, no formal sample size calculation is required for the primary endpoint. However, a minimum sample size will be estimated for multiple regression model including up to six predictors, a medium effect size (f^2=0.15), α=0.05, and power=0.80, resulting in at least 97 participants to be required [30]. Previous literature has reported dropout rates ranging from approximately 19% to 33% among individuals receiving mental health care [31]. Therefore, estimating an attrition rate of approximately 20% during follow-up, at least 116 participants will be recruited.

Recruitment procedure

Eligible participants will be screened for inclusion during routine clinical activities by nurse researchers working within participating services. All eligible individuals will receive oral and written information regarding the study and will be invited to participate. Written informed consent and authorization for personal data processing will be obtained before enrollment. To facilitate comprehension of study procedures, participants will also receive a summary version of the informed consent document.

Study timeline

Recruitment is planned over a 12-month period. Each participant will be followed for six months after enrollment, resulting in an overall study duration of approximately 18 months.

Data collection

At enrollment, participants will undergo a comprehensive nursing assessment conducted as part of routine clinical care. Although the assignment of NDs is part of routine nursing practice, participating nurses will receive preliminary training in the NANDA-I taxonomy before study initiation to improve diagnostic reliability. The assigned NDs will be discussed and confirmed by at least two trained nurse researchers. Participants will subsequently undergo two planned follow-up assessments at above described time intervals. To identify persistent, resolved, and newly occurring NDs over time, during each follow-up assessment, previously identified NDs will be re-evaluated and any newly emerged NDs will be recorded.

Study variables

In addition to NDs, all study variables will be routinely collected as part of standard nursing

Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it,* Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

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assessment through clinical interviews, physical assessment, review of clinical records, and the electronic information systems currently used within participating services.

At enrollment, sociodemographic information will be collected, including age, sex at birth, nationality, spoken language, educational attainment, parental situation, caregiving responsibilities, living arrangement, housing condition, employment or educational status, socioeconomic condition, and availability of family support. Socioeconomic condition, as routinely assessed and documented by social workers using standardized categories based on the individual's or household's economic resources relative to local income reference standards, will be categorized as high, medium, low, or absent.

Clinical variables collected at enrollment will include the service of admission, psychiatric diagnoses according to the DSM-5 classification, current prescribed and self-administered medications, history of abuse or violence, medical comorbidities assessed by General Practitioner, substance- or behavior-related addictions, primary substance or behavioral addiction, previous dropout episodes from mental health/addiction services, and involvement of healthcare, social, or judicial services. Information regarding previous episodes of care within mental health or addiction services (whether the actual study setting or different services) will also be recorded.

Data regarding pharmacological and non-pharmacological interventions implemented after enrollment will be also collected.

Clinical and organizational outcomes collected during follow-up will include the number of home-based or outpatient nursing encounters, days spent in community-based day-care programs, days of admission to Community Mental Health Centers (CMHCs), duration of psychiatric hospitalization, days spent in residential facilities, and the number of compulsory psychiatric treatments.

At the end of follow-up, participants' service status will be recorded and categorized as ongoing care, treatment completion, transfer to another service, or voluntary withdrawal from treatment (dropout).

Outcomes

The primary outcome is the epidemiological characterization of NDs during service admission, including:

prevalence of NDs; number of NDs per participant; distribution of NDs according to clinical and sociodemographic characteristics.

Secondary outcomes include: changes in NDs prevalence and distribution over time; predictors of NDs persistence or resolution. For longitudinal analyses, NDs will be classified as persistent, resolved, or newly occurring. Persistent NDs will be those identified at baseline and still present at follow-up; resolved NDs will be those present at baseline but absent at follow-up; and newly occurring NDs will be those first identified during follow-up. Changes in ND status will be assessed at 3 and 6 months.

Clinical and organizational outcomes will include: the number of home-based or outpatient nursing

Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it,* Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

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encounters; days spent in community-based day-care programs; days of admission to CMHCs and psychiatric inpatient unit; number of compulsory psychiatric treatments and their duration; care pathway status at the end of follow-up (ongoing care, treatment completion, transfer to another service, or dropout).

Data management

All sensitive participants' data (e.g. name, date of birth, age) will be pseudonymized using a progressive identification code. The correspondence table linking participant identity and study code will be stored separately and password protected. Only authorized researchers will have access to study datasets.

Statistical analysis

Normality of continuous variables will be assessed using the Shapiro-Wilk test and homogeneity of variance using Levene's test. Continuous variables will be reported as means and standard deviations or medians and interquartile ranges, as appropriate. Categorical variables will be presented as frequencies and percentages. Bivariate analyses will be performed using Student's t-test, Mann-Whitney U test, Wilcoxon signed-rank test, one-way ANOVA, Kruskal-Wallis test, chi-square test, or Fisher's exact test, as appropriate. Odds ratios with 95% confidence intervals will be reported for categorical comparisons. Pearson's or Spearman's correlation coefficients will be used to evaluate associations between continuous variables.

Because NDs will be assessed repeatedly within the same participants at enrollment, 3 months, and 6 months, longitudinal analyses will account for within-subject correlation. Changes in the number of NDs over time will be evaluated using mixed-effects regression models including participant as a random effect. When analyses are performed at the level of individual ND, clustering of multiple diagnoses within the same participant will be considered through mixed-effects or generalized estimating equation (GEE) models, as appropriate. Predictors of ND persistence, resolution, or occurrence over time will be explored through multivariable models adjusted for relevant clinical and sociodemographic characteristics.

Statistical significance will be established at $p < 0.05$. Data analyses will be performed using Jamovi and R statistical software.

Bias management

The joint assessment process conducted by two experienced nurses, together with preliminary training of nurse researchers and evaluation of inter-rater agreement in NDs assignment, is expected to substantially reduce the risk of information bias, including misclassification bias, measurement bias, and ascertainment bias. Therefore, prior to study initiation, agreement in the assignment of NDs will be evaluated using Cohen's kappa coefficient. Two nurses will independently assign NDs to a sample of 10 persons already receiving care at participating services. A kappa coefficient > 0.60 will be considered indicative of good intra- and inter-rater agreement [32].

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The consecutive enrollment of all eligible participants should ensure the recruitment of a sample whose characteristics are broadly representative of the population routinely receiving care within participating services, thereby reducing the risk of selection bias.

The observational nature of the study precludes the identification of causal relationships between NDs and outcomes of interest. Nevertheless, the collection of relevant variables that may act as potential confounders and their inclusion in multivariable statistical models will allow a more comprehensive exploration of the associations between NDs and study outcomes.

Expected results, translational relevance, and impact for the National Health System

The epidemiological description of NDs in community mental health and addiction services, together with the identification of potential associations between NDs and sociodemographic and clinical variables, as well as the impact of specific diagnostic clusters on patient outcomes, is expected to improve understanding of the evolution of patients' care needs.

The analysis of the most prevalent nursing care issues may support a more efficient allocation of healthcare resources and help identify potential training needs among nursing staff, ultimately contributing to the improvement of care quality within the National Health System.

Ethical considerations

The study will be conducted in accordance with the Declaration of Helsinki and applicable regulations governing observational research. The study protocol has been approved by the Regional Ethics Committee (Prot. 0050044/P/GEN/ARCS dated December 19, 2025). Written informed consent for study participation and personal data processing will be obtained from all participants before enrollment.

All study data will be pseudonymized, stored on protected servers, and managed in compliance with the General Data Protection Regulation (GDPR 2016/679).

Funding

No external funding was received for this study.

Conflict of interest

The authors declare no conflicts of interest.

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Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it*, Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

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Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it,* Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

Submission received: 09/09/2026
End of Peer Review process: 21/09/2026
Accepted: 22/09/2026

Milano University Press

DISSERTATION NURSING V.6, N.1, (31/01/2027)

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ISSN: 2785-7263 DOI: 10.54103/dn/32755

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Corresponding author: Claudia Fantuzzi: *cfantuzzi@units.it*, Corso di Laurea in Infermieristica, Dipartimento Universitario Clinico di Scienze Mediche, Chirurgiche e della Salute, Università degli Studi di Trieste, Strada di Fiume 447, 34149, Trieste (TS) ITALY

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