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Gender and other diversity-related factors in psychiatric hospital care: protocol for the participatory mixed-methods PSY-DIVER study

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Abstract

Background Psychiatric hospital care is multimodal and typically comprises pharmacotherapy, psychotherapy, social therapy, occupational therapy, exercise therapy, and various forms of creative therapies. The use, acceptance and effectiveness of these interventions may be shaped by gender and further diversity-related factors including age, migration background, sexual orientation, religious beliefs and socioeconomic status. The impact of such diversity-related factors on psychiatric inpatient care processes and outcomes has not been comprehensively examined in German psychiatric hospitals.

Methods PSY-DIVER is a participatory mixed-methods research project conducted by the LVR Institute for Research and Education. The project runs from 1 November 2025 to 31 October 2028 and comprises four linked components: participatory project governance including a co-creation workshop, clinical routine data analyses, qualitative interviews followed by quantitative online surveys, and a two-round Delphi process to develop recommendations for clinical practice. In the routine data component, routine data from the nine psychiatric LVR hospitals with approximately 500,000 inpatient and day-care clinic cases and 1.7 million outpatient cases from 2015 to 2024 will be analysed, with a planned extension to more recent retrospective data during the project period. Structured routine data will be enriched by automated extraction of additional diversity-related variables from clinical free text using a rule-based natural language processing pipeline and locally hosted large language models in a secure local environment. Primary data collection will include 31 semi-structured interviews with mental health service users, relatives, and professionals, as well as online surveys with approximately 300 service users, 100 relatives, and 100 professionals. Integrated findings from these project parts will inform a structured consensus process with approximately 40 professional experts and experts by experience to formulate recommendations for a more diversity-sensitive psychiatric hospital care.

Discussion PSY-DIVER is designed to generate a detailed empirical account of how gender and other diversity-related factors are associated with treatment allocation, treatment processes and treatment outcomes in psychiatric hospital care. By combining large-scale routine data, primary stakeholder data and a participatory consensus process, the study aims to provide an evidence base for more equitable and diversity-sensitive psychiatric services.

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Trial registration German Clinical Trials Register (DRKS00040088), registered on April 30, 2026.

Keywords Psychiatric hospital care, Diversity, Gender, Intersectionality, Mixed methods, Participatory research, Clinical routine data, Natural language processing, Health services research, Delphi

Background

Diversity-related factors are known to exert a profound influence on mental well-being. Individuals living in more unfavourable social circumstances are at increased risk of psychological distress and mental illness across the life course [1]. Racism and stigma-related stress adversely affect mental well-being in socially disadvantaged racial and ethnic groups [2], and in other minority groups such as sexual and gender minorities [3–5]. Moreover, diversity-related factors may intersect – meaning they overlap and interact within individuals in ways that are not merely additive – and, in many cases, intensify experiences of minority stress [6] as well as the risk of poor mental health outcomes [7, 8].

Psychiatric hospital care is a core component of the support system for people with mental illness and usually combines pharmacological, psychotherapeutic, and psychosocial interventions. Although these interventions are delivered within the same service context, their offer, uptake, tolerability, and effectiveness may vary according to diversity-related patient characteristics that extend beyond clinical characteristics alone. The aim of this study is to further elucidate the impact of diversity-related factors in psychiatric care. Developing diversity-oriented psychiatric services is increasingly important as service user populations become more heterogeneous, which can give rise to less visible or "hidden" identity dimensions that shape clinical needs and care experiences [9]. At the same time, psychiatric services occupy a central position in the pursuit of health equity, as they are responsible for delivering care that is accessible and inclusive [10]. To support clinicians in addressing these challenges, the American Psychiatric Association has issued a series of diversity-focused educational resources and "best practice" materials that aim to enhance culturally competent assessment and treatment across multiple service users groups [11]. In addition, a handbook to advance diversity and cultural sensitivity in mental healthcare has been published [12]. A central aspect of our study is to develop similar recommendations for inpatient psychiatric treatment in Germany. In this study, diversity-related factors are defined as age, migration background and nationality, gender and gender identity, physical and mental abilities, religion and belief, sexual orientation, and social background [13]. The project is informed by an intersectional perspective because several diversity-related characteristics may co-occur and interact with one another as well as with clinical variables such as diagnosis, symptom severity, and care setting [14–16].

Previous research

Gender and diversity-related aspects play a crucial role in shaping mental health outcomes, as they influence both exposure to psychosocial stressors and access to appropriate forms of support. For instance, gendered caregiving responsibilities and societal beauty ideals often impose a disproportionate burden on women, whereas male gender norms may constrain emotional expression and inhibit help-seeking behaviour in men, who more commonly exhibit externalising behaviour patterns and elevated rates of substance use disorders, that can obscure underlying anxiety or depressive disorders [17]. In addition, experiences of gender-based and sexual violence constitute a major risk factor for the development of distress and mental illness for women [17, 18]. Despite the clear relevance of these gender-related influences, they remain insufficiently addressed in psychiatric care, and there is a notable lack of studies investigating the systematic implementation and evaluation of gender-sensitive treatment approaches [19].

A substantial body of evidence exists on diversity-related aspects in psychotherapy. Studies from the UK have shown that mental health service users from ethnic minority groups and those with a migration background are less likely to make use of psychotherapy [20, 21], but that the effectiveness of psychological interventions can be substantially enhanced by specific adaptations for these service users [22]. Other diversity-related factors also appear to negatively influence psychotherapy outcomes, for example regarding Muslim service users [23] and lesbian or bisexual women [24]. Service users' educational level also seems to play a role: individuals with a higher level of education are significantly more likely to use outpatient psychotherapy and less likely to opt for a psychodynamic than a psychoanalytical approach [25]. With respect to psychosocial treatment outcomes, a review of meta-analyses did not find differences across racial and ethnic groups for some disorders, such as depression and post-traumatic stress disorder (PTSD), for which the evidence base is strong, whereas data were lacking for other disorders such as borderline personality disorder and eating disorders [26]. A scoping review on psychosocial group therapy for individuals with a range of physical disabilities showed that most studies reported high adherence rates and improvements in depression, anxiety, and overall psychological health; although

one study found increased well-being among men but decreased well-being among women [27].

Several diversity-related aspects are also known to influence psychopharmacological treatment. At the population level, women are significantly more likely than men to take psychotropic drugs [28]. In service users, female gender is further associated with a higher risk of psychotropic polypharmacy [29], even after adjustment for other service user characteristics [30]. For some psychotropic drugs, both gender-related and ethnicity-related differences in pharmacokinetics and pharmacodynamics are well-documented. Multiple differences between male and female individuals in the absorption and metabolism of antipsychotic drugs have been observed, leading to higher dopamine receptor occupancy and an increased risk of side effects in female service users [31, 32]. Ethnicity also plays an important role in the pharmacokinetics of psychotropic drugs. Non-normal metaboliser genotypes of the CYP2D6 and CYP2C19 enzymes, which are central to the metabolism of many antipsychotics, antidepressants, and benzodiazepines [33], vary considerably between countries and regions. The prevalence of non-normal CYP2D6 metabolism ranges from 2.7% in Gambia to 61% in Algeria, and is estimated at 46% in Germany; for CYP2C19, rates of non-normal metabolism range from 80% in India to 32% in Mexico [34]. In clinical practice, these differences may lead to substantially higher plasma levels of drugs such as haloperidol, clozapine, quetiapine, and aripiprazole in people with East Asian ethnicity compared with those from North American and Western European populations [35]. In addition, clinical decision-making appears to vary according to diversity-related characteristics. In a Spanish study, after adjustment for multiple factors, migration background was associated with higher use of long-acting injectable (LAI) antipsychotics among service users with schizophrenia [36].

Diversity-related aspects are also relevant in the application of coercive measures. A systematic review and meta-analysis showed that men are at higher risk of involuntary psychiatric hospitalisation than women [37]. During involuntary psychiatric hospitalisation, male gender likewise appears to be associated with a higher risk of seclusion and physical restraints [38–40]. Evidence on gender and coercive medication in inpatient psychiatric care is less consistent [38, 39, 41]. Individuals from ethnic minority groups have been found to be at higher risk of involuntary hospitalisation [42] as well as physical restraint [43].

With respect to treatment satisfaction among mental health service users with a migration history, study findings are mixed, with some suggesting higher and others lower satisfaction [44, 45]. Qualitative research highlights the importance of social identity in mental health care, which refers to the aspect of an individual's self-concept that derives from membership in social groups, together with the emotional and evaluative significance attached to that membership [46, 47]. Furthermore, a persistent gender disparity has been observed, with men tending to attribute greater shame and blame to phases of mental illness and to regard psychotherapy as less beneficial than women [48]. In addition, transgender service users continue to report experiences of stigmatisation within psychiatric inpatient settings [49].

Objectives of this study

Despite numerous studies on diversity-related aspects of psychotherapy, psychopharmacology, psychosocial interventions and other components of psychiatric treatment such as coercive measures, evidence on the real-world implementation of diversity-sensitive psychiatric care — particularly inpatient care — remains limited. The primary objective of this study is therefore to identify diversity-related differences in psychiatric hospital care, with particular attention to psychopharmacological prescribing, monitoring of adverse drug effects, psychotherapy and psychosocial intervention density, and treatment outcomes. A second objective is to examine how diversity-related factors interact with one another and with clinical variables within an intersectional framework. A third objective is to derive practical recommendations for more diversity-sensitive psychiatric hospital care.

A further objective is methodological. The project will develop and test approaches for extracting diversity-related information from free-text clinical documentation using natural language processing (NLP) procedures. By employing rule-based feature extraction and large language model (LLM) approaches, additional diversity-relevant characteristics such as migration background, educational status and homelessness will be extracted from medical histories documented in the hospital information system and used as additional variables in routine data analyses. Compared with manual evaluation, this method offers the advantage of scalability and the opportunity to analyse large datasets. In rule-based feature extraction, frequently occurring *n-grams* (text segments comprising one or more words) are reviewed and assigned to a predefined classification. Using this approach to identify sociodemographic characteristics, sufficient predictive accuracy has already been demonstrated using healthcare data from the USA [50]. LLM-based approaches to feature extraction from clinical anamnesis texts have also shown promising results. Good predictive accuracies were obtained for feature extraction from the United States Medical Licensing Examination Step 2 Clinical Skills dataset through fine-tuning based on annotations and explicit consideration of the risk of hallucinations [51]. However, replication using

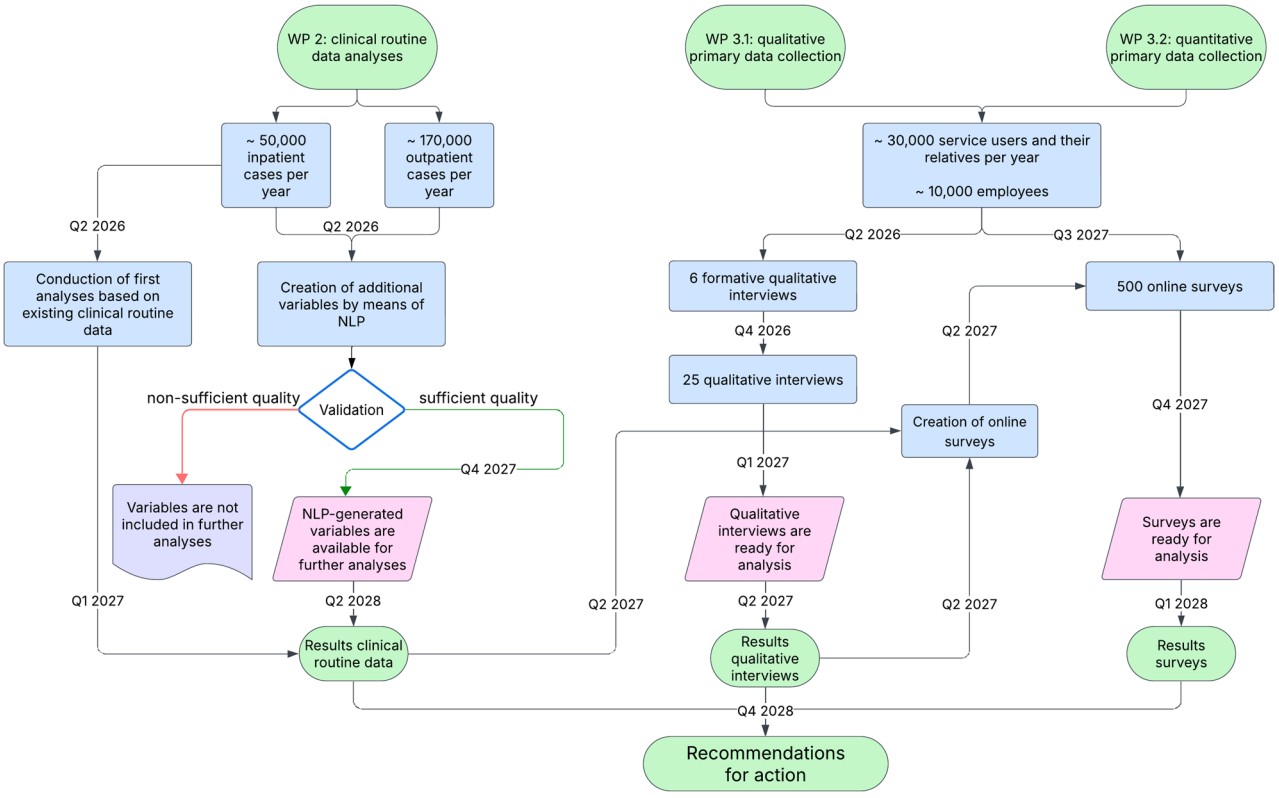

Fig. 1 Flowchart of the project PSY-DIVER – NLP = natural language processing; WP = working package; Q = quarter

German-language routine psychiatric documentation has not yet been demonstrated. If successful, this approach may provide a transferable model for future clinical routine data research in psychiatry and other clinical settings.

The overarching research questions are threefold. First, which gender- and diversity-related inequalities can be identified in psychiatric hospital care, and how do these factors interact with diagnosis and other clinical variables? Second, which barriers and facilitators of gender- and diversity-sensitive care are perceived by service users, their relatives, and mental healthcare professionals? Third, which consensus recommendations for routine practice can be derived from the combined evidence base?

Methods

Setting

PSY-DIVER is a participatory mixed-methods study that combines quantitative and qualitative work packages and links them sequentially and iteratively. The project is non-interventional and comprises retrospective observational analyses of clinical routine data, primary qualitative and quantitative stakeholder research, and a Delphi-based consensus process. The flowchart of the project is presented in Fig. 1.

The study is conducted by the LVR Institute for Research and Education and uses clinical routine data from nine communal psychiatric hospitals in the federal state of North Rhine-Westphalia (NRW), Germany. These hospitals, operated by the Rhineland Regional Council (*Landschaftsverband Rheinland* – LVR), provide inpatient and outpatient mental health care for a catchment population of approximately 4.4 million people, with an annual inpatient and day-care clinic caseload of approximately 50,000 and an annual outpatient caseload of approximately 170,000. This study protocol adheres to the Good Reporting of A Mixed Methods Study (GRAMMS) guidelines [52].

Work package 1: Project coordination

This work package concerns overall project coordination including preparation (data protection and ethics approvals) and organisation of consensus processes and the final project report. It also encompasses continuous liaison with the project steering group and the scientific advisory board throughout all project phases. The steering group consists of experts by experience, relatives of mental health service users, and mental health professionals.

Work package 2: Clinical routine data analysis

A defined set of hospital routine data is transferred to a database that serves quality assurance purposes and

is also used for research. At transmission from hospital servers to this database, patient information is pseudonymised. The initial clinical routine data observation period spans 1 January 2015 to 31 December 2024, with a planned extension to additional retrospective data from 2025 onwards during the course of the project. As shown in a previous study, the Day mix index (DMI) of the participating hospitals, a measure of disorder severity and length of inpatient stay, is comparable to the DMI of a sample of 74 psychiatric hospitals in the states of North Rhine-Westphalia, Bavaria and Saxony-Anhalt [53].

Two local computational approaches will be developed and compared. The first is a rule-based NLP pipeline using open-source software libraries, and the second consists of locally hosted LLMs operated on a secure workstation. Data will not be transferred to external services for this purpose. Both text-processing approaches will be iteratively refined and validated against manual review of randomly selected pseudonymised cases. Variables that do not achieve sufficient predictive accuracy will be excluded from substantive analyses.

An initial hybrid natural language processing approach is employed to anonymise the text. The pipeline integrates rule-based techniques, such as regular expression patterns and predefined dictionaries, with named entity recognition (NER) implemented using the FLAIR framework [54]. The rule-based component identifies clearly sensitive information, including dates, telephone numbers, and ward names, whereas FLAIR detects personal names, locations, and organisations. A protected medical terminology list is additionally incorporated to minimise the risk of inadvertently removing clinically relevant terms. The pipeline is executed locally and is iteratively reviewed to enhance the quality of anonymisation while preserving the medical content of the text.

The clinical routine data hypotheses include whether women are more frequently affected by psychotropic polypharmacy, whether gender- and age-related differences exist in weight-adjusted dosing of drugs with known metabolic differences, whether adverse drug effects and related monitoring differ by gender and age, whether therapy density differs by gender and socioeconomic status, whether brief crisis admissions and readmissions are more common in socially disadvantaged groups, and whether homelessness is associated with greater use of LAI antipsychotic formulations. Primary and secondary endpoints for the clinical routine data component therefore include the number of psychotropic substances at discharge, dose per kilogram body weight, use of therapeutic drug monitoring, QTc interval and laboratory parameters, treatment density per week, length of stay, frequency of admission, readmission, and time to readmission. The exact hierarchy of outcomes may be further refined during the participatory process and in response to findings from early qualitative work.

Statistical analyses will begin with descriptive summaries of the sample and sociodemographic characteristics. Inferential analyses will include regression-based models of group differences and associations, survival analyses for readmission-related outcomes, and exploratory machine-learning approaches such as random forest models to identify more complex patterns. Analyses will be conducted using R and Python.

Work package 3: Stakeholder interviews and surveys

Work package 3 addresses questions that cannot be answered using clinical routine data alone, especially those concerning experiences, expectations, communication and decision-making of service users, relatives, and mental health professionals. It comprises a qualitative interview phase followed by a quantitative online survey phase. The survey phase is explicitly designed to build on both the qualitative findings and the emerging routine data results.

The qualitative phase begins with six formative interviews, comprising two mental health service users, two relatives of services users, and two mental health professionals. These interviews are intended to test feasibility and identify relevant themes for refining the interview guides. They will be followed by 25 additional semi-structured interviews with service users, mental health professionals, and relatives, yielding 31 qualitative interviews in total.

Eligible participants for the interview and survey components are adults aged 18 years or older who are either clinically active professionals in psychiatric care, people with at least one inpatient or day hospital treatment over the past three years, or relatives of people with psychiatric treatment experience. Exclusion criteria include acute self-harm or risk to others that would preclude participation, and severe cognitive impairment or delirium such that informed consent is not possible. For the qualitative phase, sufficient German language proficiency is required to understand the study information and respond to interview questions, although translated materials may be provided where appropriate.

Recruitment of service users and their relatives will rely on informational flyers, self-selection via a study contact route or online link, and dissemination through the LVR clinics, trialogue forums and patient or relatives' organisations as needed. This strategy is intended to reach both internal and community-based stakeholders relevant to psychiatric hospital care.

Interviews will be conducted either in person at LVR sites or online via video conference. The interviews will be audio-recorded and transcribed by an external professional transcription service. The planned interview

duration is approximately 75 min including explanation of the study and written informed consent procedures. Qualitative analysis will be performed using MAXQDA applying an inductive–deductive approach informed by Mayring and Kuckartz [55, 56]. Coding will be performed by two researchers experienced in qualitative healthcare research and discrepancies will be resolved by discussion.

The survey phase will include approximately 500 participants, comprising around 300 service users, 100 relatives and 100 professionals. The questionnaires will be developed iteratively by the project team in dialogue with the steering group and will draw on findings from both work package 2 and the qualitative interviews. The survey content will cover sociodemographic and clinical characteristics, attitudes towards diversity-sensitive care, knowledge of diversity-related aspects of treatment, and subjective perceptions of service users' own treatment experience. Where clinical routine data or interview findings suggest potential underutilisation, overutilisation or misallocation of care, these hypotheses will also be examined in the surveys.

Survey analyses will include descriptive and inferential methods. Post-stratification of service users' and relatives' surveys according to sociodemographic and clinical characteristics of the affected person, and stratification of professional surveys by age, sex and occupational group using internal staff statistics, will be undertaken where feasible. This approach is intended to improve interpretability of survey results and reduce distortions arising from uneven participation across stakeholder groups (self-selection bias).

Work package 4: Delphi consensus process

The final phase is a structured consensus process intended to translate empirical findings into practical recommendations. Draft recommendations developed by the project team and steering group derived from the clinical routine data and stakeholder project phases will be rated in a two-round anonymous online Delphi process. The Delphi panel will include approximately 40 participants, among them mental health clinicians, people with lived experience, relatives of mental health service users, people with migration-related experience, and people from queer communities.

In the first round, panellists will rate proposed recommendations in terms of relevance and feasibility and provide free-text comments. After revision by the project team based on this feedback, a second round will be conducted to achieve final consensus. The final deliverable of the project will be a set of consensus-based recommendations for more diversity-sensitive psychiatric hospital care.

Integration of mixed-methods findings

The study design is mixed-methods not only because it includes both qualitative and quantitative data, but also because each component is intended to inform the others. The qualitative phase can refine or extend clinical routine data hypotheses, while the routine data analyses may identify patterns that require explanation from stakeholder perspectives and targeted exploration in the surveys. The Delphi phase then integrates the resulting evidence into a practice-oriented consensus process.

Sample size considerations

For the clinical routine data analyses, no formal sample size calculation is required because all eligible cases in the database over the observation period will be included. The size of this dataset will allow subgroup analyses across diagnostic and diversity-related characteristics, although statistical power to detect significant differences between patient groups may be limited for combinations of patient variables with low frequencies in the dataset. The qualitative sample is guided by heterogeneity and depth rather than statistical power and includes key stakeholder groups necessary to capture contrasting perspectives on psychiatric care. The interview contents will be checked for information saturation. The survey targets have been set to permit structured descriptive and inferential analyses across the three main stakeholder groups.

Data management and protection

The LVR Institute for Research and Education statistics database uses a layered architecture with three separate table spaces. The first table space serves for handling clinical data and the pseudonymisation processes, the second one is for pseudonymised text data with an elevated risk of re-identification and the last one is for de facto anonymised, structured (i.e. tabular) analysis data. Access is governed by role-based permissions for data trustees, database managers and analysts.

Within this architecture, identifiable data are kept separate from research datasets, while structured data made available to analysts are pseudonymised and de facto anonymous from the perspective of research staff. Free-text processing is restricted to a protected environment, and only the validated structured variables extracted from the text are transferred for substantive analysis. The data protection framework also specifies automated removal of potentially identifying information from free texts, restricted access within the LVR network, and defined retention and deletion rules for linkage keys and processed data.

For the clinical routine data study, individual informed consent is not required under German legislation. For interviews and surveys, participation is voluntary and based on informed written consent, with the option to

withdraw at any time. Reimbursement will be provided in the form of vouchers for interview participants outside LVR employment and for survey participants. A travel accident insurance policy has been arranged for interview participants who travel specifically for the study.

Dissemination

Dissemination activities will include the development of practical recommendations for psychiatric hospitals and communication of results to scientific, clinical and other stakeholder audiences. Dissemination will comprise both academic outputs and service-oriented recommendations. The explicit aim is to support more rational, evidence-informed and diversity-sensitive psychiatric hospital care in Germany.

Discussion

The PSY-DIVER project has several notable strengths. First, it integrates large-scale clinical routine data with primary qualitative and quantitative stakeholder data, enabling questions of diversity-sensitive psychiatric care to be addressed within a single work programme. Second, it incorporates participation from people with lived experience of mental health service use, their relatives and mental healthcare clinicians, which enhances the practical relevance of the final recommendations. Third, it includes a novel attempt to derive diversity-related variables from free-text clinical documentation while keeping all data processing within a secure local infrastructure. Routine data can identify large-scale patterns in treatment and outcomes, while interviews and surveys can help clarify whether these patterns reflect communication problems, knowledge gaps, barriers to access, professional assumptions, or other mechanisms. The additional Delphi phase strengthens the translational value of the project by moving beyond observation and interpretation towards structured recommendations for practice.

The study also has limitations. As in all clinical routine data research, validity depends on the quality and completeness of documentation, and some diversity-related characteristics may be incompletely recorded or difficult to infer reliably from free text. Some extracted variables may therefore fail validation and cannot be included in the final analyses. The qualitative and survey components are vulnerable to selective participation, which may affect representativeness even when multiple recruitment channels are used.

Abbreviations

DMI Day mix index
LAI Long-acting injectable
LLM Large language model
LVR Rhineland Regional Council/ *Landschaftsverband Rheinland*
NER Named entity recognition
NLP Natural language processing
PTSD Post-traumatic stress disorder

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Author contributions

SJP, AS, JZ, CS and EG-M: conceptualisation of this study. SJP, SK, MA, AS, AA, MFF, JZ, CS and EG-M: drafting the article, revising the article critically for important intellectual content, final approval of the version to be published.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the North Rhine Medical Association (no. 2026038). Data collection and analysis follow the Declaration of Helsinki. The trial was registered with the German Clinical Trials Register on April 30, 2026 (no. DRKS00040088).

Consent for publications

NA.

Competing interests

The authors declare no competing interests.

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