STUDY PROTOCOL

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Predicting dropout and non-response to psychotherapy for personality disorders: A study protocol focusing on therapist, patient, and the therapeutic relationship

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Abstract

Background The abandonment of psychotherapeutic treatments is influenced by various factors, including patient characteristics, therapist traits, and the therapeutic relationship. Despite the well-documented importance of these factors, limited empirical research has focused on the role of the therapeutic relationship and the characteristics of therapist-patient dyads in predicting treatment dropout. This study protocol outlines a longitudinal research project aimed at predicting dropout and non-response in psychotherapy for individuals with personality disorders. The research seeks to identify predictive factors related to psychotherapy outcomes, focusing on patient, therapist, and dyadic elements. Specifically, the study will examine the influence of therapist characteristics (e.g., personality traits, countertransference, responsiveness) on treatment outcomes, explore the impact of relational factors (e.g., treatment expectations, epistemic trust, therapeutic alliance) on therapy effectiveness, and assess how the therapeutic alliance within therapist-patient dyads affects the likelihood of dropout and non-response.

Methods The longitudinal study will include 100 therapist-patient dyads (200 participants) recruited from various Mental Health Services in Milan, Italy. Validated instruments will be administered to both patients and therapists at four-time points: T0 (baseline), T1 (3 months), T2 (6 months), and T3 (1 year). Data will be collected at baseline and at the one-year mark to evaluate the relationships between therapist, patient, and dyadic factors and treatment outcomes.

Discussion Identifying predictive variables associated with high dropout rates can help preempt treatment discontinuation, reducing the financial and operational burdens on mental health services. Understanding these factors will enable the development of targeted interventions to improve treatment engagement and reduce attrition. This approach could enhance outcomes for individuals with personality disorders and lead to more efficient resource allocation and sustainable delivery of mental health care.

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Introduction

Personality disorders (PDs) can be defined as a habitual pattern of inner experience and behavior that deviates (a) markedly from the expectations and norms of the subject's culture; (b) is stable and long-lasting, typically onset in adolescence or early adulthood (persisting into adulthood); (c) is inflexible, pervasive, maladaptive, and pervasive in a variety of situations (personal and social), not limited to individual episodes; (d) manifests in at least two areas of the individual's functioning (cognitive, affective, interpersonal, volitional-personal); (e) causes significant distress and functional impairment in the individual with considerable suffering, although this may manifest in an advanced stage of the disorder; (f) is not connected to other mental disorders, substances or drugs, or a general medical condition [1]. Due to severe functional impairments, the risk of suicide, frequent self-harm (especially in cluster B), and extensive use of treatments, personality disorders (PDs) are considered one of the costliest mental disorders both in terms of healthcare [2] and social costs [3].

Psychotherapy is considered the primary and elective treatment for PDs [4, 5].

Substantial progress has been made in recent decades in the development and scientific validation of treatments for PDs, especially borderline personality disorder (BPD) [6].

However, it is documented that approximately half of the patients with PDs do not respond to psychotherapy [7], and the commitment to their treatment remains high, with dropout rates ranging from 22.3% to 29.9% [8, 9].

Among the potential predictors of dropout and non-response, patient variables (measured at the time of intake) have been more thoroughly examined. According to a recent meta-analysis, commitment to change and impulsivity predict dropout [10]. Subsequent studies have consistently confirmed a significant influence of impulsivity [11, 12] and have indicated other predictive factors such as non-acceptance of emotional responses [13], mindfulness [14], reflective function [15], comorbidity with substance abuse [12, 16], history of suicide attempts [17], and age [16].

Regarding non-response to psychotherapy, a systematic review identified symptom severity before treatment as a negative predictor of response [18]. A more recent review concluded that factors related to non-response are poorly defined and inconsistently reported in the literature [7].

In addition to patient factors, the therapeutic alliance has traditionally been studied as a predictor of psychotherapy response [19–21] and dropout [11, 12, 22]. Some studies have shown that therapist-related factors (such as experience, training and skills, and emotional support) can influence dropout rates [23]. In this regard, there has been increasing attention to the therapist's contribution to the therapeutic relationship [24], with a growing interest in "therapist responsiveness" - defined as the therapist's behavior influenced by the emerging context [25] - and the therapist's management of their emotional responses [26, 27].

Despite the well-documented influence of patient characteristics on psychotherapy outcomes [28–30], much less attention has been given to the dynamic interaction between therapists and patients. Limited empirical research has explored how the therapeutic relationship and specific characteristics of therapist-patient dyads contribute to treatment dropout and non-response. Notably, no studies have systematically considered the characteristics of therapists or the interactions within therapist-patient dyads, nor have experimental or longitudinal designs been employed to track these factors over time. Given the critical role of the therapeutic alliance in successful outcomes, understanding the combined influence of both patient and therapist factors is crucial for developing more effective, tailored interventions. This gap in the literature underscores the need for comprehensive research that examines not only individual factors but also the dyadic interactions that shape therapy success or failure.

Aims

The primary aim of this longitudinal research is to identify predictive factors of psychotherapy success and failure, considering elements related to the patient, therapist, and therapeutic dyad (patient/therapist). Specifically, the research sets out the following objectives: (a) to examine the association between positive outcomes (symptomatic improvement) and negative outcomes (dropout and non-response) and therapist factors (therapist personality characteristics, countertransference, and responsiveness) over time; (b) to examine the association between positive/negative outcomes and relational factors (treatment expectations, epistemic trust, therapeutic alliance); and (c) to investigate the impact of the level of therapeutic alliance within the therapist-patient dyad on psychotherapy outcomes.

It is hypothesized that greater therapist responsiveness, positive treatment expectations, epistemic trust, and a high level of therapeutic alliance will correspond to positive outcomes (e.g., symptom improvement). Moreover, the study aims to identify predictive variables of therapy

Table 1 Patient assessments according to the time of psychotherapy

Outcomes	T0: Baseline	T1: three months from treatment beginning.	T2: six months from treatment beginning.	T3: after one year from the treatment beginning.
Maladaptive personality traits (PID-5)	X			X
Working Alliance (WAI– P)	X	X	X	X
Responsiveness (PEAR)	X			X
Epistemic Trust (ETMCQ)	X	X	X	X
Mentalized Affectivity (MAS)	X	X	X	X
Symptoms (SCLK-9)	X		X	X
Interpersonal Problems (IIP-32)	X		X	X

Table 2 Therapist assessments according to the time of psychotherapy

Outcomes	T0: Baseline	T1: 3 months	T2: 6 months	T3: 12 months
Personality (BFQ)	X			
Countertransference (TRQ)	X		X	X
Working Alliance (WAI-T)	X	X	X	X
Epistemic Trust (ETMCQ)	X	X	X	X
Mentalized Affectivity (MAS)	X	X	X	X

success and failure, confirming the therapeutic alliance as a key predictor of treatment success across time.

Methods
Participants
Participants will be recruited at different Mental health services of Milan, Italy (November 2024 – June 2025). Inclusion criteria are outlined below to participate in the study. Patients: (a) aged 18–45; (b) ability to speak adequate Italian; (c) ability to provide informed consent; (d) diagnosed with a personality disorder; (e) under treatment for at least one month. Exclusion criteria will include (a) organic brain disease; (b) diagnosis of a developmental disorder; or (c) a documented history of developmental delay or intellectual disability. Therapists: (a) registration with the professional register of psychologists and psychotherapists; (b) specialization in psychotherapy obtained at least 2 years prior.

Instruments
A sociodemographic questionnaire will be proposed, followed by validated instruments. The self-report instruments to be administered are outlined below. Timing and administration schedules are provided in Tables 1 and 2.

Big Five Questionnaire 2 [31]. This instrument comprises 132 items forming five scales (energy, friendliness, conscientiousness, emotional stability, openness to experience), each consisting of 24 items. Respondents indicate their agreement with the extent to which each item describes them on a five-point scale ranging from complete disagreement (1=very untrue for me) to complete agreement (5=very true for me).

Personality Inventory for DSM-5 Brief Form [32]. The self-report questionnaire was developed to assess the personality trait criteria (Criterion B - dysfunctional personality traits) of Section III of the DSM-5 to adopt a dimensional approach. It consists of 25 items rated on a four-step scale ranging from 0 (Very False or Often False) to 3 (Very True or Often True). It captures 5 main trait domains named: Negative Affectivity, Detachment, Antagonism, Disinhibition, and Psychoticism.

Therapist Response Questionnaire [33] evaluates the countertransference (or therapist emotional response). This is a clinical report consisting of 79 items (5-point Likert scale) measuring a wide range of thoughts, feelings, and behaviors expressed by therapists towards their patients, considering various dimensions of countertransference (Helpless/Inadequate, Overwhelmed/Disorganized, Positive/Satisfying, Parental/Protective, Special/Overinvolved, Criticized/Devalued, Hostile/Angry, Sexualized, and Disengaged).

The Working Alliance Inventory [34] is a self-report instrument capable of measuring the quality of the therapeutic alliance from the perspectives of both patients and therapists. It assesses three key aspects of the therapeutic alliance: (a) agreement on therapy tasks, (b) agreement on therapy goals, and (c) development of an affective bond.

The Patient's Experience of Attunement and Responsiveness Scale [35] is a 30-item self-report measure (3-point Likert scale) of therapist attunement and responsiveness, as reported by both the therapist and the patient.

The Epistemic Trust, Mistrust, Credulity Questionnaire [36] is a self-report tool consisting of 15 items that assess epistemic trust. The ET-CMQ is based on a three-factor structure composed of distinct dimensions: (a) trust, referring to an adaptive attitude in which the individual is adequately open to opportunities for social learning; (b) mistrust, reflecting the tendency to treat any source of information as unreliable; and (c) credulity, referring to a pervasive lack of discrimination and clarity about one's own position.

The Mentalized Affectivity Scale [37] is a 35-item self-report instrument to measure affective mentalization, i.e., the capacity to mentalize in the process of emotional regulation. The MAS detects 5 dimensions: Identification of emotions, Expression of emotions, Curiosity about emotions, Elaboration of emotions, and Autobiographical memory.

The Symptom Checklist K9 [38] is a 9-item self-report measure of symptomatic distress. The scale is a brief form of the SCL-90 [39]. On a 5-step scale ranging from not at all (0) to extremely [4], respondents indicate whether they have experienced, over the past week, a list of psychological symptoms (e.g., "feeling tense or agitated").

The Inventory of Interpersonal Problems [40] is a 32-item self-report instrument – on a Likert scale from 0 (not at all) to 4 (extremely) – measuring distressing interpersonal behaviors that the respondent identifies as "hard to do" (i.e., behavioral inhibitions) or "do too much" (i.e., behavioral excesses). It provides an overall score and 8 subscale scores: Dominant/Controlling – tendency to be controlling or manipulative in interpersonal interactions; Vindictive/Self-Centered – tendency to be egocentric and hostile in relationships with others; Cold/Distant – tendency to experience minimal affection and weak bonds with others; Socially inhibited/Avoidant – avoidance and social anxiety and difficulty approaching others; Non-assertive – difficulty expressing one's needs and expressing one's needs to others; Overly accommodating/Exploitative – tendency to be gullible and easily take advantage of people; Self-sacrificing/Overly nurturant – tendency to be excessively altruistic, generous, trusting, caring, and permissive towards others; Intrusive/Needy – tendency to impose one's needs and have difficulty respecting others' boundaries.

Procedures
The instruments will be administered using the pen-and-paper method. Eight packets containing the questionnaires will be created (one per session, differentiated for patients and therapists). Some instruments will be administered to both patients and therapists, while others will be exclusively administered to either the patient or the therapist (see Table 2).

The measurements will be collected at four-time points: T0: baseline; T1: after 3 months from the start of treatment; T2: after 6 months; T3: after one year of treatment. All instruments will be administered at baseline (T0) and after one year from the start (T3). After three months (T1), the TRQ (only to the therapist), ET-MCQ, and MAS will be administered. After six months (T2), the TRQ (only to the therapist), ET-MCQ, MAS, SCL-K9 (only to the patient), and IIP-32 (only to the patient) will be evaluated. The WAI will be administered every three months (T0, T1, T2, T3) to assess the evolution of their therapeutic alliance.

It will be the responsibility of the researchers to pair questionnaires of patients and therapists. Questionnaires (those addressed to therapists and those addressed to patients) will contain two codes (one referring to the respondent and one referring to the respective therapist/patient). The questionnaires for patients and therapists will be paired based on the codes indicated in their respective questionnaires.

Sample size estimation and statistical analysis
200 participants are needed (100 dyads composed of 100 patients and 100 therapists). Specifically, three estimations have been conducted, each of which corresponds to each specific research objective.

Sample size calculation to address Objective 1 (unit of measurement: therapists). To calculate the necessary sample size, G*Power was utilized. To achieve a significant relationship with a power of .95 in a multiple linear regression (for a true effect size of .5 and $p = .05$), 93 therapists will be required. Recent studies have demonstrated that the dropout rate in this type of study is approximately 25% [9, 41]. Therefore, even if 25% of these individuals (i.e., 19) were to withdraw, there would still be enough participants (i.e., 74) to detect an effect. In any case, missing data will still be included in subsequent measures and managed with imputation models.

Sample size calculation to address Objective 2 (unit of measurement: patients). To calculate the necessary sample size, G*Power was utilized. To achieve a significant relationship with a power of 0.95 in a multiple linear regression (for a true effect size of .5 and $p = .05$), 93 patients will be required. Recent studies have demonstrated that the dropout rate in this type of study is approximately 25% [9, 41]. Therefore, even if 25% of these individuals (i.e., 19) were to withdraw, there would still be enough participants (i.e., 74) to detect an effect. Again, missing data will be included in subsequent measures and managed with imputation models.

Sample size calculation to address Objective 3 (unit of measurement: dyads). Dyads will be treated with multilevel statistical models (MLM). For our dyadic data, the group size is 2. Considering the work conducted by Du & Wang [42] – which examines the effects of the number of dyads, intraclass correlation (ICC), proportion of singletons, and the missingness mechanism on convergence, bias, coverage rates, and type I error rates of parameter estimates in dyadic data analysis using MLMs – the required number of dyads will be 100 [Proportion of Singletons = 30%, for ICC = 0.1].

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Location

Recruitment will be entirely voluntary. Individuals will be recruited at the Mental Health Services of the north of Italy close to Milan. The sites of interest will be Youth Mental Health Service for Early Intervention at Niguarda Hospital, Rodense Mental Health Service, Ovest Milanese Mental Health Service, and Psychoanalysis Milanese Centre. A poster will be displayed indicating the contact details of the researchers and the methods through which to participate in the research.

Discussion

In recent years, there has been a notable rise in the number of patients with Personality Disorders (PD) seeking treatment within Italian Mental Health Services (MHS), prompting several regions to implement tailored treatments [43]. Nevertheless, the planning of PD treatment is predominantly influenced by anecdotal insights or contextual factors about healthcare systems (such as availability and costs) and treatment providers' backgrounds (medical versus psychological). At best, treatment plans are informed by fragmented scientific evidence lacking a coherent justification. This study aims to contribute to the development of a scientific rationale to guide clinicians in treatment planning, focusing on preventing nonresponse and dropouts among PD patients. Specifically, it seeks to empower clinicians to identify early on those clients who may require additional or alternative support to engage effectively in treatment. The study results will be utilized to formulate clinical guidelines for predicting the course of PD psychotherapy based on individual factors and therapist responses.

Advancing our understanding by identifying predictive factors of psychotherapy failure in PDs aligns with the principles of "precision medicine" [44], an approach emphasizing subgroup targeting over individualized treatment. By identifying patterns of variation within patient subgroups, actionable insights can be gleaned, guiding the selection of interventions tailored to specific patient profiles [45–47]. This proposal contributes to the broader endeavor of tailoring treatments to match specific case characteristics.

Moreover, given the significant challenges posed by PDs and their associated high rates of hospitalization or incarceration, these disorders rank among the most financially burdensome mental health conditions, both in terms of public health and social costs [2, 3]. Therefore, from an economic standpoint, increasing the number of patients benefiting from available treatments is a critical challenge that must be addressed. The findings of this study have direct implications for improving resource allocation within mental health services.

In conclusion, while the effectiveness of psychotherapy in producing positive outcomes across various domains has been well-established [48], our understanding of the mechanisms underlying its efficacy remains limited [49].

Abbreviations
BPD   Borderline Personality Disorder
PDs   Personality disorders

Author contributions
OO, IM, AG, GF, and MRI developed the first version of the project. FDS and CR write the proof of the article, were responsible for implementing, conducting, and collecting project data.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Participants will receive detailed written and oral study information before providing written informed consent. This project was approved by the Ethics Committee of the Catholic University of Sacred Hearth (protocol number: 94/24).

Competing interests
The authors declare no competing interests.

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