Trials

STUDY PROTOCOL

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Assessing the effectiveness and the feasibility of a group-based treatment for self-stigma in people with mental disorders in routine mental health services in North-East Italy: study protocol for a pragmatic multisite randomized controlled trial

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Abstract

Background Self-stigma refers to the process whereby individuals with mental disorders internalize negative societal attitudes and misconceptions about mental health conditions, potentially affecting their sense of self-worth and identity. This internalization can significantly impact various aspects of life, including treatment engagement, personal relationships, and overall well-being. Narrative Enhancement and Cognitive Therapy (NECT) was developed in the United States to counteract self-stigma and has been supported by multiple randomized controlled trials. However, NECT has not yet been implemented in Italy or within a public mental health system grounded in community psychiatry. This study aims to evaluate the efficacy and feasibility of the Italian version of the NECT within the public mental health sector in a large part of North-East Italy.

Methods and analysis This pragmatic, multisite, superiority, randomized, wait-list controlled trial with two parallel arms will recruit over four hundred patients with severe mental disorders from 26 public community-based mental health centers in North-East Italy. The experimental intervention, NECT, consists of 20 group-based sessions to reduce self-stigma. The study will assess NECT's impact on several psychological dimensions, including self-stigma levels (primary outcome), self-esteem, hope, empowerment, recovery perception, mental well-being, and stigma stress (secondary outcomes). Feasibility will be evaluated by collecting data on participant adherence and treatment implementation, including eligibility screening, participation rates, intervention completion, exposure levels, and reasons for dropout.

Discussion The findings of this research are expected to contribute to the understanding of effective treatments for patients with mental disorders, particularly those burdened by high levels of self-stigma, and to improve their recovery outcomes.

Trial registration ClinicalTrials.gov; Identifier: NCT06567145.

Keywords Self-stigma, Quality of life, NECT, Recovery, Severe mental illness anti-stigma intervention

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Introduction

Background and rationale

Research conducted on the general population indicates that people generally hold misconceptions and negative stereotypes about individuals with mental disorders [1]. For example, 60% of the population believes that patients with mental disorders are aggressive or violent, and 50% think they are incapable of working [2]. On the other hand, research has found that most people with mental disorders are aware of the presence of these stereotypes in society, and over 70% expect to be treated unfairly by others due to their disorder [3, 4]. Additionally, 60–70% of patients with mental disorders believe that most people would refuse to have someone with a mental disorder as a friend, neighbor, coworker, or partner [5, 6]. Although some individuals with mental disorders may respond to these stereotypes with indifference or anger, a large proportion accept these stereotypes as true, internalize them, and attribute them to themselves; this process is known as internalized stigma or self-stigma [7]. The Health Stigma and Discrimination Framework [8] provides a global perspective on the shared mechanisms of stigma across health conditions, emphasizing its impact on health outcomes and access to care. Within this framework, internalized stigma emerges as a key process through which societal stereotypes are internalized, contributing to diminished self-esteem, reduced hope, and poorer recovery outcomes.

One of the largest studies in this field, involving 1,229 people with schizophrenia spectrum disorders across 14 European countries, estimated that 41% exhibit a high level of self-stigma, which was found to be associated with lower levels of empowerment, higher perceived discrimination, and reduced social contact [5]; other studies have reported substantially similar rates [6, 9].

Research has consistently found that self-stigma is associated with poorer recovery outcomes [10]. A recent meta-analysis reports significant correlations between self-stigma and lack of hope, self-esteem, and self-efficacy, as well as lower subjective quality of life, greater symptom severity, and reduced treatment adherence [11]. Self-stigma can be both a consequence and a cause of negative outcomes. When self-stigma plays a causal role, it may represent a target for treatment. Yanos and colleagues [12] proposed the "illness identity model," which offers a set of detailed and testable hypotheses regarding the potential causal role that self-stigma plays in influencing recovery outcomes in people with mental disorders. This model suggests that when identity is influenced by self-stigma, individuals believe that recovery is not possible, thereby reducing hope (i.e., expectations about their future) and self-esteem [13]. Despair and low self-esteem, in turn, increase the risk of suicide, reduce social interaction, lead to the use of passive coping strategies for dealing with symptoms, and reduce treatment adherence. As patients increasingly rely on avoidant coping strategies, they may also lose their jobs. Finally, avoidant coping style, social isolation, and reduced social functioning can exacerbate the severity of psychotic symptoms. Empirical support for this model comes from the results of two studies conducted by different research groups [14, 15].

Building on evidence of the role that self-stigma plays in recovery processes, Narrative Enhancement and Cognitive Therapy (NECT) was developed in the United States in 2007–2010 as a manualized treatment aimed at reducing self-stigma in people with mental disorders. NECT is a structured group treatment that combines psychoeducation (with the goal of helping participants challenge their stigmatizing beliefs about mental illness and recovery with empirical and scientific data), cognitive restructuring (focused on teaching skills to modify self-stigma-related negative beliefs), and narrative enhancement (focused on helping participants improve their ability to integrate themes such as trust and self-worth into their personal narratives). To date, five studies have been published that have tested the efficacy of NECT. The first, conducted in the United States on a small group of 39 patients, did not reveal significant effects of NECT on self-stigma, likely due to the small sample size; however, the intervention was found to be feasible and well-tolerated by participants [16]. A subsequent quasi-experimental study conducted in Israel on 119 patients with serious mental illness demonstrated that participation in the NECT program was associated with significant improvements in self-stigma, self-esteem, quality of life, and hope with small-to-medium effect sizes reported for these outcomes, providing support for the use of NECT as an effective treatment on this population [17]. Similarly, a randomized controlled trial with a 6-month follow-up conducted in Gothenburg, Sweden, involved a sufficiently large sample size ($n=106$) to detect significant improvements in self-stigma and self-esteem, which were maintained at six months. This study reported medium effect sizes for the primary outcomes, further supporting the efficacy of NECT [18]. A larger randomized controlled study conducted in the United States on 170 patients with schizophrenia spectrum disorders provided robust statistical power to detect differences between groups. It demonstrated significant improvements in self-stigma and other variables, including avoidant coping style, compared to the supportive control intervention with moderate-to-large effect sizes for these outcomes [19]. Finally, a randomized controlled trial implemented in Taiwan on 86 patients with chronic schizophrenia showed more significant results from NECT in improving self-stigma and

anticipated discrimination compared to the control intervention with medium effect sizes reported, indicating clinically meaningful changes [20]. Together, these studies demonstrate that the efficacy of NECT is supported by robust empirical evidence across diverse contexts and populations, qualifying it as an evidence-based intervention and suggesting its widespread implementation.

Self-stigma is a significant issue for individuals suffering from severe mental disorders treated within Italian mental health services. Barlati et al. [21] found that nearly one-fourth of people with schizophrenia receiving rehabilitative interventions exhibited high self-stigma. This self-stigma was associated with experiencing more medication side effects (e.g., extrapyramidal symptoms) and worse subjective well-being. Additionally, a nationwide study of a large sample of patients with schizophrenia found that internalized stigma was significantly associated with greater overall symptom severity [22] and increased depression [23], with resilience playing a mediating role in this relationship. Furthermore, self-stigma was shown to diminish the positive effects of social capital on empowerment among people with major depression receiving treatment within mental health services [24].

Unfortunately, in Italy, interventions aimed at reducing self-stigma among individuals with mental disorders are not consistently provided. When such interventions are available, they often lack a strong foundation of evidence-based efficacy [25]. This gap is partly due to the absence of manualized interventions like NECT in the Italian language. Additionally, the self-stigma interventions documented in the literature have primarily been tested in geographic regions and healthcare systems that differ significantly from Italy's mental health services, which are rooted in a public community-based psychiatry model. These differences raise concerns about the applicability and effectiveness of such interventions within the Italian context.

Objectives

The present study aims to: (1) evaluate the effectiveness of this approach in the clinical routine of community-based mental health centers (CMHCs); (2) test the feasibility of the new Italian version of the NECT treatment among patients attending CMHCs in a large area of northeastern Italy. Overall, this project will increase knowledge about optimal treatments for patients with mental disorders burdened by high self-stigma to improve their recovery outcomes.

Trial design

This is a pragmatic, multisite, superiority, randomized, wait-list controlled trial with two parallel arms. The study will evaluate the effectiveness and the feasibility of the NECT intervention, as manualized in the Italian version developed by our group [26], among patients with severe mental disorders treated by community-based mental health centers (CMHCs) who exhibit at least a moderate level of self-stigma. Participants will be randomized into one of two groups: NECT intervention group or the wait-list control (WLC) group. Since the study is designed as an 'add-on' trial, patients in both the experimental and control groups will continue to receive routine care provided by their respective mental health services. As the trial in a real-world clinical setting, it follows a pragmatic design.

The study protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [27] and the TIDieR checklist [28]. The completed SPIRIT checklist is provided as Appendix 3, and the completed TIDieR checklist is included as Appendix 4.

Methods

Study setting

Participants for this study will be recruited from public Community Mental Health Centers (CMHCs) located in the Veneto region, which has a population of approximately 4.9 million, the Autonomous Province of Trento with around 538,000 inhabitants, and the city of Bolzano, home to approximately 107,000 inhabitants.

Routine care

Participating CMHCs typically offer a comprehensive range of integrated community care services, including pharmacological interventions and, where necessary, psychosocial treatments such as individual or group cognitive behavioral therapy (CBT), family psychoeducation, cognitive rehabilitation, and supported employment [29–31]. Throughout the study period, the research staff will systematically collect and document detailed information on the specific interventions received by participants.

Eligibility criteria

Eligible participants must be adults aged 18 years or older and have a clinical diagnosis of schizophrenia, schizoaffective disorder, schizoid disorder, schizophreniform disorder, bipolar disorder type I or II, or major depressive disorder according to DSM-5 criteria. Additionally, participants are required to be stabilized outpatients, defined by a period of at least three months of clinical stability with no changes in pharmacological treatment during this time. The exclusion criteria include: (1) individuals who had received or are receiving interventions specifically targeting self-stigma during the study period;

(2) those unable to provide informed consent, (3) individuals with intellectual disabilities; (4) those with a primary diagnosis of personality disorder or substance dependence; (5) individuals with limited proficiency in written and spoken Italian.

All eligible patients will be screened using the Internalized Stigma of Mental Illness (ISMI) scale. Only those who score above 1 on a scale from 0 to 3, indicating at least moderate levels of self-stigma, will be invited to participate in the study, following Yanos et al. [19].

Regarding the intervention, it will be administered by routine mental health staff employed at the participating CMHCs. The intervention, as outlined by the NECT authors, is suitable for delivery by mental health professionals, including psychologists, psychiatric rehabilitation therapists, and professional educators, who possess documented experience in mental health settings. These criteria ensure that the study is conducted within a well-defined population, by appropriately qualified professionals, thereby enhancing the validity and reliability of the findings.

Informed consent will be obtained by qualified mental health professionals from the study team at participating CMHCs. These professionals will provide a clear explanation of the study, answer any questions, and ensure that participants or their authorized surrogates fully understand the study's details. Participants or surrogates will sign a consent form, with the process being carefully documented and forms securely stored according to ethical guidelines.

Interventions

Two comparison treatments have been chosen for this study.

Experimental condition

The experimental treatment is the Narrative Enhancement and Cognitive Therapy (NECT), a manualized intervention developed in the early 2000s by American authors Philip Yanos, David Roe, and Paul Lysaker, designed for small groups of individuals with severe mental disorders [26]. For the present study, the Italian version of the NECT manual, produced by our team with the authorization and assistance of the original authors, will be used [26]. The development process of the Italian version of the manual involved: (a) the translation of the original manual; (b) the discussion of the translation within two multidisciplinary focus groups (comprising mental health professionals from various backgrounds, psychiatric service users, family members, volunteers, and former users) to assess its relevance, adequacy, and comprehensibility; (c) the back-translation of the final Italian version; and (d) the review of the back-translation by the American authors, leading to final approval.

The NECT intervention consists of 20 sessions, divided into five parts. In the first part, the orientation phase (2 sessions), participants are invited to describe themselves and reflect on their experiences with the illness and their relationship to it. The second part (3 sessions) includes a psychoeducation component that addresses the concepts of stigma and self-stigma (or internalized stigma). During this phase, participants explore myths and stereotypes associated with mental disorders, based on scientific evidence, and reflect on their personal experiences of public stigma and the consequences of internalizing such stereotypes. The third part (7 sessions) focuses on learning cognitive restructuring techniques to identify and challenge self-stigmatizing false beliefs. The goal is to equip participants with tools to manage and reduce the impact of internalized stigma, promoting a greater sense of self-efficacy, control over their lives, and hope for the future. This section also aims to provide specific coping skills to address social anxiety and mood deflation related to self-stigma. The fourth part (7 sessions) centers on narrative enhancement, which encourages participants to share and reflect on their personal stories. This process helps participants find meaning in their experiences, including those related to mental illness, and develop a new perspective on their personal history. This part of the program appears to have the most lasting impact on improving hope and self-esteem. Finally, the intervention concludes (1 session) with an activity similar to the initial session, where participants are asked to describe themselves and their relationship with their illness, allowing them to reflect on changes in self-perception and their relationship with the illness that occurred during the group process. The comparison between the "old" and "new" identities developed during the group work is intended to give participants a sense of the change achieved, thereby lightening the burden of self-stigma.

The NECT intervention will be delivered in a face-to-face format, exclusively in small group sessions. All sessions will take place at the participating Community Mental Health Centers (CMHCs), with each group consisting of up to eight participants. The intervention is not designed for individual or remote delivery. The NECT intervention will be delivered in dedicated group rooms within participating Community Mental Health Centers (CMHCs). These rooms are equipped to ensure privacy and confidentiality during the sessions and are furnished to facilitate group discussions.

Each session of the program lasts approximately one hour and is divided into three phases: introduction, main content, and conclusion. The introduction, lasting about 5–10 min, involves the facilitator

summarizing the topics covered in the previous session and encouraging participants who were absent to review the material. The facilitator then asks if they had the opportunity to reflect on the previous week's topics and if they applied any of the skills learned outside the group. Finally, the facilitator outlines the session's timing and topic. The main content phase, lasting about 40–45 min, involves discussing 2–3 pages of the manual. Participants are encouraged to voluntarily read 2–3 sentences from the text, followed by a group discussion to process the material and reflect on their personal experiences. In the concluding phase, the facilitator spends 5–10 min summarizing the key themes discussed, connecting them to the group's reflections, and encouraging participants to practice what they have learned during the week. It is suggested that two facilitators be present to enhance the fidelity of the intervention. In such cases, one facilitator takes the primary role—responsible for tasks such as taking attendance, distributing workbooks, and guiding the session—while the co-facilitator provides constructive comments, emotional support, and assistance to participants with reading or writing difficulties. No risks from NECT are reported, so no specific monitoring will occur. NECT poses no harm, and participants will continue with their regular clinical care. It should be noted, as previously mentioned, that the experimental intervention is an add-on to the routine care that patients will continue to receive throughout the study.

The intervention will utilize paper-based support materials. Each participant will receive an Italian version of the Participant's Workbook, while the two facilitators will be provided with the Facilitator's Guide, both specifically developed to support the delivery of the NECT intervention. Participants will be free to write in their workbooks throughout the group sessions, and at the end of the intervention, the Participant's Workbook will remain with them as a personal resource. The materials will be distributed during the first group session and securely stored at the intervention site in a locked cabinet, accessible only to the facilitators.

Control condition

Patients assigned to the wait-list condition will continue receiving routine care within their usual care settings, which typically include psychopharmacological therapy, follow-up visits for medication management, potential individual sessions with psychologists or psychotherapists, and possible participation in rehabilitation groups, all in line with each patient's individualized care plan.

Training of clinicians participating in the study

The NECT intervention will be implemented by professionals designated by the directors of the participating CMHC. The staff assigned to the experimental group will reallocate a portion of their time from nonspecific rehabilitation interventions to the NECT intervention. This reallocation will not result in additional workload or financial burden for the participating CMHC.

The NECT intervention will be delivered by two facilitators for each group, selected from mental health professionals working at the participating CMHCs. These professionals will include psychologists, psychiatric rehabilitation therapists, and professional educators with documented experience in delivering group interventions and cognitive-behavioral approaches.

All clinicians involved in the study will attend a one-day training session led by the authors of the Italian version (A.L. and L.B.) and the lead author of the original American version of the program (P.T.Y.). The training will include discussions and role-playing exercises, with corrective feedback provided by the trainers.

The personnel involved in the study will also be responsible for recruiting patients and conducting evaluations using the questionnaires specified in this protocol. Therefore, these professionals will be trained in the use of the questionnaires and scales during an online training session that will take place after the NECT intervention training. Before the start of recruitment, the personnel responsible for the evaluations must undergo an inter-rater reliability exercise for the administration of the SCID-5 [32].

Assessment of treatment fidelity

Treatment fidelity will be assessed by the research staff at the coordinating center for each participating group, using audio recordings from one session per module (Psychoeducation, Cognitive Restructuring, and Narrative Enhancement). Intervention adherence will be assessed through the proportion of sessions conducted according to the manualized protocol. Audio recordings from selected sessions will be reviewed using the Italian version of the NECT Fidelity Scale, and any deviations from the protocol will be documented. Additionally, regular supervision sessions will be held throughout the study period to provide facilitators with corrective feedback and ensure consistency across sites. The research team will also track session attendance and completion rates to evaluate the extent to which the intervention was delivered as planned. The evaluation of these audio recordings will employ the Italian version of the NECT Fidelity Scale [19]. This structured tool assesses various dimensions related to the delivery

of the intervention on a 5-point Likert scale (from 1 "poor" to 5 "excellent").

The evaluated dimensions will include: a) group structure (number of participants—maximum of 8; duration of each session—maximum of 1 h); b) facilitator activities (session structuring, adherence to the manual and use of educational materials, effectiveness in teaching, interpersonal skills, time management, handling challenging moments, active exploration of session topics); c) orientation phase (creating a climate of hope, defining self-stigma, presenting the group's goals, providing an overview of the intervention and explaining its rationale, describing potential benefits of participation, briefly explaining how these benefits are achieved); d) Psychoeducation (stigma and its impact, self-stigma and its impact, myths about mental illness, disclosure of mental illness, sharing personal experiences, imparting new knowledge, exploring participants' personal experiences); e) Cognitive Restructuring (modeling thoughts and emotions, linking negative emotions to thoughts, traditional cognitive restructuring approaches to examine evidence, adopting alternative perspectives on the situation, focusing on judgmental tendencies in thoughts, internal dialogue, integrating group discussions into daily life); f) Narrative Enhancement (encouraging participants to write and share their stories, showing interest and enthusiasm for the stories, helping participants see themselves as active characters in their stories, using "narrative tips," and employing the guide to provide feedback on the stories); g) conclusion phase (summarizing the themes discussed, connecting them to reflections that emerged during the group, and encouraging participants to apply what they have learned during the week).

This comprehensive evaluation will ensure that the NECT intervention is delivered consistently and effectively across all participating sites. Regular group supervision sessions will be also organized throughout the duration of the study.

Outcomes

Primary outcome

Differences in the level of self-stigma (or internalized stigma) as measured by the total score on the Internalized Stigma of Mental Illness (ISMI) between the NECT group and the control group over time (change from baseline [T0] to the end of treatment [T1]).

Secondary outcomes

a) Effectiveness

Differences between the NECT group and the control group over time (change from baseline [T0] to the end of treatment [T1]) in the total scores of the following instruments:

- Rosenberg Self-Esteem Scale (RSES) (self-esteem);
- Beck Hopelessness Scale, 9-item version (BHS-9) (hope);
- Boston University Empowerment Scale (BUES) (empowerment);
- Recovery Assessment Scale (RAS) (perception of recovery);
- Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS) (mental well-being);
- Stigma Stress Scale: difference between the damage item score and the coping resources item score (stigma stress).

b) Feasibility

- Percentage of patients meeting the ISMI screening criteria;
- Percentage of patients who agree to participate in the study;
- Percentage of patients who complete the intervention;
- Percentage of patients "exposed" to NECT (i.e., those who completed at least 6 sessions or at least one of the following phases: Psychoeducation, Cognitive Restructuring, or Narrative Enhancement).

Assessment instruments

- Self-stigma (or internalized stigma) will be assessed using the Internalized Stigma of Mental Illness (ISMI) scale [33], the most widely used scale internationally [34]. This self-report questionnaire consists of 29 items rated on a four-point Likert scale and is divided into five subscales: (1) Alienation: feeling devalued as a member of society; (2) Stereotype Endorsement: agreement with negative stereotypes about mental illness; (3) Discrimination Experience: perceived current discriminatory treatment attributed to others' prejudice; (4) Social Withdrawal: avoiding others due to mental illness; (5) Stigma Resistance: perceived ability to counter stigma. The scale provides an overall mean score and five subscale scores. Higher scores indicate higher levels of self-stigma. The overall scale and the five subscales have consistently shown high reliability and validity (except for the 'Stigma Resistance' subscale) [34].

- Self-esteem will be assessed using the Rosenberg Self-Esteem Scale (RSES) [35], the most widely used measure of self-esteem in the literature. This self-report scale consists of 10 items rated on a four-point Likert scale. The total score, obtained by summing the item scores, reflects the level of self-esteem, with higher scores indicating higher self-esteem. The scale has demonstrated good psychometric properties [36, 37].
- Hope will be measured using the Italian short version of the Beck Hopelessness Scale (BHS-9) [38, 39], a self-report questionnaire consisting of 9 items rated on a binary scale (true/false). The total score is the sum of all responses (range 0–9), with higher scores indicating a greater level of hopelessness.
- Subjective experience of empowerment will be assessed using the Italian version of the Boston University Empowerment Scale (BUES) [40, 41]. This self-report questionnaire consists of 28 items rated on a four-point Likert scale. Higher scores indicate greater empowerment. The items are organized into five subscales: (1) Anger, (2) Optimism and Control over the Future, (3) Self-Esteem/Self-Efficacy, (4) Power/Perceived Powerlessness, and (5) Community Activism and Autonomy. The scale has shown high internal consistency and good factorial validity in both the original [36] and Italian versions [37].
- Perception of recovery will be assessed using the Italian version of the Recovery Assessment Scale (RAS) [42, 43], a self-report scale consisting of 20 items distributed across five factors: (1) Personal Confidence and Hope; (2) Willingness to Ask for Help; (3) Goal and Success Orientation; (4) Reliance on Others; and (5) Not Being Dominated by Symptoms. All RAS items are rated on a five-point Likert scale. The scale provides an overall score as well as five subscale scores.
- Mental well-being will be assessed using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [44], a questionnaire consisting of 14 items rated on a five-point Likert scale. Higher total scores indicate better mental well-being.
- Stigma stress will be assessed using the two-item short version of the original eight-item Stigma Stress Scale [45]. One item assesses perceived stigma-related harm ("Prejudice against people with mental disorders will affect many aspects of my life"), and the other assesses perceived resources to cope with stigma ("I am able to resist and cope with the problems arising from prejudice against people with mental disorders"). Each item is rated on a seven-point Likert scale. Stigma stress is calculated as the difference between the scores of the two items (harm score minus coping resources score). Higher scores indicate greater stigma-related stress.

Collection of feasibility data

To assess the feasibility of the study, the following information will be collected regarding adherence to and implementation of the treatment at the participating CMHCs:

(a) The number of patients who meet the ISMI screening criteria compared to the number of patients who meet the inclusion and exclusion criteria.
(b) The number of patients who, among those eligible, agree to participate in the study.
(c) The number of participants who have completed the intervention, along with the reasons for any participant withdrawals.
(d) The proportion of participants who are considered "exposed," meaning those who attended at least 6 sessions in total or completed at least one of the following phases: psychoeducation, cognitive restructuring, or narrative enhancement [16, 19].
(e) The perspectives of participants and facilitators on factors that may facilitate or hinder the implementation of the intervention, such as the organization of the intervention, the facilitators' skills, or the content of the materials. To gather this information, a custom questionnaire will be used, developed based on the instrument proposed by Oudejans et al. [46].

Participant timeline

Information on enrolment, intervention, and assessment in the trial can be found in Table 1.

There will be two assessment points. At baseline (T0), socio-demographic information (sex, age, education level, employment status, and marital status) and clinical data (clinical diagnosis, age of onset, duration of care with the current service provider, ongoing pharmacological and psychological treatments) will be collected, along with scales evaluating the primary and secondary outcomes (see below). Additionally, researchers will administer the Structured Clinical Interview for DSM-5 (SCID-5). At the end of the intervention (T1), the scales assessing the primary and secondary outcomes will be administered again.

Participants in the NECT intervention will also be monitored for their attendance at group sessions, any decision to discontinue the treatment, and the reasons for discontinuation.

At the end of the intervention, for the experimental group only, the perspectives of participants and

Table 1 Enrolment, interventions and assessments of the study

	Study period			
	Enrolment	**Allocation**	**Pre-treatment**	**Post-treatment**
	T_{-2}	T_{-1}	T_0	T_1
Eligibility criteria	X			
ISMI > 1 screening	X			
Informed consent	X			
Randomization		X		
Socio-demographics characteristics			X	
Clinical characteristics			X	
SCID-5			X	
INTERVENTIONS				
Treatment condition (NECT)			X	X
Control condition			X	X
NECT ASSESSMENTS				
Number of sessions				X
Reason for discontinuation				X
ASSESSMENTS				
Self-stigma (ISMI)			X	X
Self-esteem (RSES)			X	X
Hope (BHS)			X	X
Empowerment (BUES)			X	X
Perception of recovery (RAS)			X	X
Mental well-being (WEMWBS)			X	X
Stigma and stress			X	X

facilitators will be gathered on factors that may facilitate or hinder the implementation of the intervention, such as the organization of the intervention, facilitator skills, or content of the materials. For this purpose, a questionnaire developed specifically for this study, based on the one proposed by Oudejans et al. [46], will be used.

Sample size

The intervention NECT will be implemented at 26 CMHCs. Each center will recruit 16 patients for randomization who meet the inclusion and exclusion criteria, have screened positive, and have consented to participate. Thus, the total sample size will be 416 patients, with 208 per arm. The power analysis, conducted using G*Power 3.1.9.7, indicates that this sample size will be enough to detect a Cohen's d effect size of 0.27 for the total ISMI score (where d = 0.20 indicates a small effect and d = 0.50 indicates a medium effect), with alpha = 0.05 and 1-Beta = 0.80. After considering a potential 25% attrition rate in both study arms (giving 156 patients each), the sample size will be enough to detect a Cohen's d effect size of 0.32. Two previous trials [16, 19] estimated a Cohen's d effect size of 0.37 and 0.50, respectively, for the total ISMI score, so it is predicted that the target sample size will be adequately powered to detect a change in the ISMI.

Recruitment procedure

The trial will start following the approval of this protocol by the coordinating center and all participating CMHCs. Recruitment will last for 2 months, the intervention will extend over 5 months, and an additional 5 months will be required for data entry, database verification, data analysis, and manuscript preparation. Therefore, the total duration of the study is 12 months. A schematic overview of the study design is presented in the flow diagram shown in Fig. 1.

The research staff at each participating CMHC will conduct a review of their patient roster, as of the recruitment start date, to identify those who meet the inclusion and exclusion criteria. These patients will be screened using the Internalized Stigma of Mental Illness (ISMI) scale [33]. Those who score above 1 (on a scale from 0 to 3), indicative of at least moderate levels of self-stigma [18], will be presented with the project and asked to

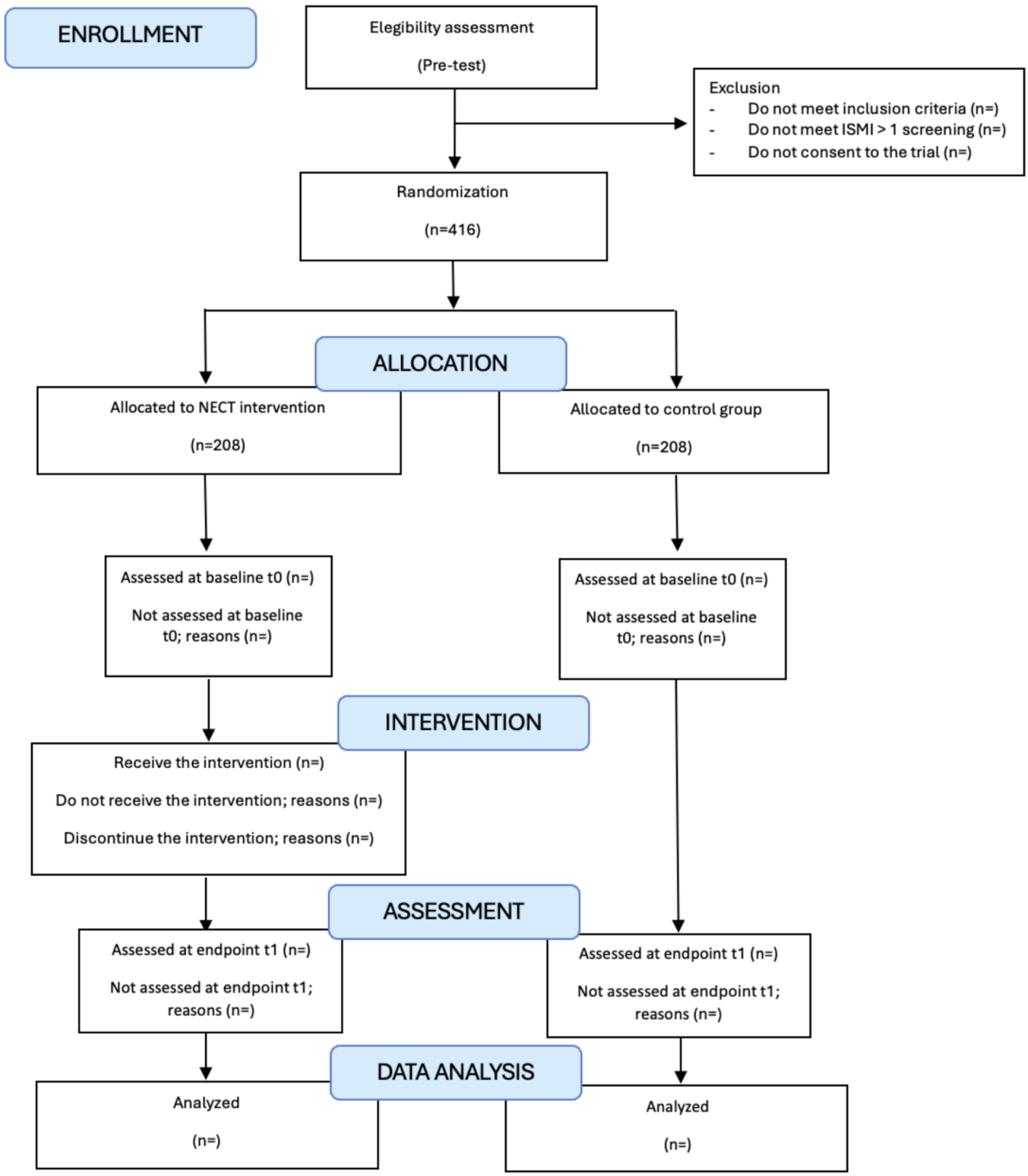

Fig. 1 Flowchart of the trial design

provide informed consent. Researchers will aim to recruit and randomize 16 patients per CMHC, as the NECT intervention requires, according to its manual, that it be administered in groups of 8 patients. The list of patients who consent to participate in the study will be sent, in anonymized form, to the coordinating center, which will perform stratified randomization by CMHC. Following this phase, each CMHC will proceed with the administration of baseline assessment tools (T0).

Assignment of interventions: allocation

Each CMHC will provide the statistician at the coordinating center with an anonymized list of 16 patients who will satisfy the eligibility criteria, will be positive for the screening (ISMI > 1), and will have signed informed consent to participate in the RCT. Each CMHC will independently manage the attribution of the codes to the 16 patients in ascending order by enrolment data. The trial statistician will perform a separate randomization procedure within each CMHC (stratification by site) by applying a blocked randomization procedure with a 1:1 allocation ratio. The randomization scheme will be generated using Stata software (version 17; StataCorp, College Station, TX, USA) with the 'ralloc' command (random allocation of treatments in controlled trials). For each CMHC, the Stata command will be 'ralloc block size treat, nsubj [16] seed(#CMHC identifier) saving(sequence#CMHC) idvar(id_#CMHC)', which will allocate treatments A (NECT) and B (waiting list) at random in a ratio of 1:1 in blocks of sizes 2, 4, 6, 8 and 10 to 16 subjects. Block sizes will be allocated unequally in the ratio 1:4:6:4:1 (Pascal's triangle). The seed will be set at the integer identifying each CMHC in the list of participating sites (1 for Belluno, 2 for Feltre, etc.) (Table 2).

Stratified randomization by CMHC will be applied primarily for practical reasons related to the feasibility of the trial, as it is challenging to offer CMHCs the option to be part of the control group, particularly given that training for all CMHC staff on the NECT intervention will be conducted in a single day. The use of stratified randomization by mental health centers guards against potential imbalances due to unknown factors related to the specific characteristics of the centers (such as organization, staff, and context). This approach should reduce the variance of the outcome difference between the two groups and, consequently, help increase statistical power with respect to simple randomization [47].

Table 2 List of participating CMHCc with the number of patients per group

Centers	NECT intervention (n)	Control Condition (n)
1. CMHC Belluno	8	8
2. CMHC Feltre	8	8
3. CMHC Treviso	8	8
4. CMHC Pieve di Soligo	8	8
5. CMHC Asolo	8	8
6. CMHC Venezia	8	8
7. CMHC San Donà	8	8
8. CMHC Rovigo 1	8	8
9. CMHC Rovigo 2	8	8
10. CMHC Badia Polesine	8	8
11. CMHC Padua	8	8
12. CMHC Monselice	8	8
13. CMHC Alto Vicentino 1	8	8
14. CMHC Alto Vicentino 2	8	8
15. CMHC Vicenza	8	8
16. CMHC Verona UOC1	8	8
17. CMHC San Bonifacio	8	8
18. CMHC Bussolengo	8	8
19. CMHC Legnago	8	8
20. CMHC Verona South	8	8
21. CMHC Trento UO North	8	8
22. CMHC Trento UO East	8	8
23. CMHC Trento UO South	8	8
24. Bolzano 1	8	8
25. Bolzano 2	8	8
26. Villa San Pietro (Trento)	8	8
TOTAL	**208**	**208**

Assignment of interventions: blinding

Given the nature of the trial, subjects involved in the RCT (patients and clinical staff) can't be blinded to allocation. Self-report questionnaires will assess primary and secondary outcomes, so this RCT will not involve outcome assessors. The final data will be communicated to the trial statistician (working at the coordinator center), who will also be responsible for the allocation procedure. Also, blinding for the data analyst cannot be applied.

Data collection and management

The assessments specified by the study will be conducted on paper forms, which will be sent to the coordinating center in an anonymized format (with each participating CMHC assigning a code). The coordinating center will handle the data transfer to digital files, oversee the storage of paper documents, ensure the consistency and accuracy of the data, and perform statistical analysis in an aggregated format. Access to the data file will be restricted to the research staff designated in this protocol or personnel directly authorized by Prof. Antonio Lasalvia.

Statistical method

Categorical variables will be described using frequencies (%), and continuous variables will be presented as means (SD). Categorical variables will be analyzed using Chi-square tests, and continuous variables will be analyzed using independent samples t-tests.

Effect size will be calculated using Cohen's standardized d. Main effects (group and time) and interactions (group × time) will be estimated using mixed-effects models, which account for correlations between repeated measures and for missing data. To account for potential

covariates' effects (including the center and patients' baseline characteristics), models will be estimated with (adjusted models) and without (unadjusted models) them. Analyses will be conducted using the intention-to-treat (ITT) approach.

Subsequently, an exploratory analysis will be performed, including only patients in the NECT group who meet the criteria for being classified as 'exposed.' Results will be reported according to CONSORT guidelines. A post hoc power analysis will be conducted based on the actual effect size for the ISMI. All tests will be two-tailed with a significance level of 0.05. Statistical analyses will be performed using Stata 18 for Windows.

Oversight and monitoring

As there are no reported data in the literature regarding potential risks or adverse effects associated with participation in the NECT intervention, no specific monitoring will be implemented, no interim analyses will be performed, and no stopping guidelines will be applied. Conceptually, the NECT psychological intervention does not include elements that could harm participants' well-being. Additionally, it is important to note that all participating patients will continue to receive clinical monitoring and care from their respective local treatment teams.

Protocol amendments

Important protocol modifications, such as changes in aims, primary outcome, study design, method of allocation, sample size, and statistical analysis, will be notified and amended to the Ethics Committee of the South-West Veneto Area, which approved the trial, and to the ClinicalTrials.gov, where the trial was registered, and transparently described in trial reports and publications.

Dissemination plans

The results will be presented in international peer-reviewed journals if accepted. The principal investigators, co-investigators, and other professionals involved in the proposed intervention will be the authors of any publications. The criteria established by the International Committee of Medical Journal Editors will be adopted. Entitlement to authorship will be based on the participants' substantive contribution to the study design, data analysis, and interpretation, the writing of the article, its critical revision, and final approval before submission.

Discussion

This trial seeks to evaluate the effectiveness of the NECT on self-stigma among patients receiving care within the Italian community-based mental health system. The primary analysis will examine whether between-group differences in self-stigma outcomes exceed what would be expected by chance, with particular attention to whether these differences reach clinically meaningful thresholds from the patient's perspective. Secondary outcomes will help elucidate the mechanisms underlying any observed effects.

We acknowledge that null findings are possible and valuable outcomes that can inform future implementation efforts. Should the results not support NECT's effectiveness in this context, such findings would contribute important insights about: (a) the intervention's transportability across healthcare systems; (b) potential cultural adaptations needed for the Italian context; (c) implementation barriers in community-based mental health settings.

We also recognize the potential for expectation effects, where participants in the intervention group may perform better due to their awareness of receiving the treatment. However, this study incorporates several design elements to minimize and control for expectation effects, including (a) the use of a wait-list control group, which helps manage general expectancy effects, as both groups anticipate receiving the intervention—while the experimental group immediately undergoes NECT, the control group remains in routine care with the expectation of receiving the intervention after the trial period; (b) the structured, manualized delivery of NECT, combined with fidelity assessments, to ensure consistency in how the intervention's implementation across sites, thereby reducing variations in delivery that could influence expectancy effects based on facilitator enthusiasm or style; (c) standardized assessment procedures across both groups. These measures are designed to reduce bias and enhance the reliability of our findings by ensuring observed effects are more directly attributable to the intervention itself.

If significant effects are observed, this study could inform decisions about integrating NECT into routine care within Italian mental health services. This integration could improve patient outcomes, reduce the social and personal impacts of self-stigma, and contribute to more comprehensive and effective mental health care strategies. Additionally, the study may be crucial for assessing NECT's efficacy and feasibility outside its original context in the United States and beyond the settings where it has been previously evaluated. By implementing and evaluating NECT within a different healthcare system, this study will offer insights into its adaptability and effectiveness across different cultural and healthcare contexts, potentially guiding future adaptations and implementations in other international settings.

Trial status

This protocol (version 1.0) was registered at ClinicalTrials.gov on August 20, 2024 (NCT06567145). The present trial has not yet started. The recruitment will begin on October 1, 2024, with an estimated study completion date of September 30, 2025.

Appendix

World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov; Identifier: NCT06567145
Date of registration in primary registry	20 August, 2024
Secondary identifying numbers	––
Source(s) of monetary or material support	No external funding will be provided The study will be supported by personal funding of each investigator from the University of Verona
Primary sponsor	No sponsor
Secondary sponsor(s)	No sponsor
Contact for public queries	Prof. Antonio Lasalvia, PhD, MD telephone: + 39 045 8283911 e-mail: antonio.lasalvia@univr.it
Contact for scientific queries	Prof. Antonio Lasalvia, PhD, MD Section of Psychiatry, Department of Neuroscience, Biomedicine and Movement Sciences, University of Verona Policlinico "G.B. Rossi" P.le Scuro, 10 37134 – Verona, Italy
Public title	A group-based treatment for self-stigma in people with mental disorders in north-east Italy
Scientific title	Assessing the effectiveness and feasibility of group-based treatment for self-stigma in people with mental disorders: a pragmatic multisite randomized controlled trial in routine mental health services in north-east Italy
Countries of recruitment	Italy
Health condition(s) or problem(s) studied	Stigma, mental disorders, self-stigma
Intervention(s)	Experimental intervention: Narrative Enhancement and Cognitive Therapy Control intervention: Control group
Key inclusion and exclusion criteria	Inclusion Criteria:- Participants must be 18 years or older- Individuals must have a diagnosis of schizophrenia, schizoaffective disorder, schizoid disorder, schizophreniform disorder, bipolar I or II disorder, or major depressive disorder, according to DSM-5 criteria- Participants must be outpatients with clinical stability for at least 3 months, with no changes in pharmacological treatment during this period- Participants must have sufficient knowledge of written and spoken Italian- Participants must score above 1 on the ISMI (Internalized Stigma of Mental Illness) scale, indicating at least moderate levels of self-stigma Exclusion Criteria:- Individuals unable to provide informed consent are excluded- Participants with intellectual disabilities are excluded- Individuals with primary diagnosis of personality disorder or substance dependence condition are excluded- Participants engaged in other programs that could influence self-stigma (e.g., social cognitive rehabilitation, social skills training) during the study are excluded
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: no blinding Primary purpose: treatment
Date of first enrolment	October 2024
Target sample size	416
Recruitment status	Not yet recruiting
Primary outcome(s)	Differences in the level of self-stigma (ISMI) between pre-treatment and post-treatment
Key secondary outcomes	Change between pre-treatment and post-treatment on the following dimensions:- Self-esteem (RSES)- Hope and expectations about the future (BHS-9)- Empowerment (BUES)- Recovery perception (RAS)- Mental wellbeing (WEMWBS)- Stigma as stressor- Screeing rate- Elegible rate- Exposure rate- Perceptions of implementation factors

Abbreviations

NECT	Narrative enhancement cognitive therapy
CMHCs	Community mental health centers
ISMI	Internalized stigma of mental illness
RSES	Rosenberg self-esteem scale
BHS-9	Beck hopelessness scale, 9-item version
BUES	Boston university empowerment scale
RAS	Recovery assessment scale
WEMWBS	Warwick and Edinburgh mental wellbeing Scale
DSM-5	Diagnostic and statistical manual of mental disorders, 5th edition
ITT	Intention-to-treat
SPIRIT	Standard protocol items: recommendations for interventional trials
SCID-5	Structured clinical interview for DSM-5 disorders
REC/IRBs	Research ethics committees/institutional review boards
NICE	National institute for health and care excellence

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08739-4.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Authors' contributions
AL, CB, LB, PY designed the study. AL and CB are responsible for the acquisition of data. CB, AL, LB, PY are responsible for the analysis and interpretation of data. AL drafted the manuscript. All authors were involved in revising the manuscript. All authors read and approved the final version of the manuscript. All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication.

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Data availability
The data file will not be publicly available. An anonymous copy of the data file of this study will be available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The study protocol will be conducted to ensure adherence to the principles of Good Clinical Practice and procedures and to comply with Italian laws, as described in the following documents and agreed upon by the study investigators:
1. ICH Harmonized Tripartite Guidelines for Good Clinical Practice 1996.
2. D. L. n.211 del 24 giugno 2003.
4. D. L. n.200 6 novembre 2007.
5. D.M. 21 dicembre 2007.
6. Legge n.189 8 novembre 2012.
7. SPIRIT "Standard Protocol Items: Recommendations for Intervention trials".
The trial will be conducted according to the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO).
Eligible participants will be told that they can withdraw from participating in the study when they change their mind in the time between having contact with the researcher, filling in the questionnaire and participating in the study as well as during the study.
Data entry by study participants using the online process will be protected by the following measures:
- network protection through a firewall;
- encrypted Internet connection with digital certificate (SSL technology);
- server on which the database is located protected by a periodically changed password;
- access to the database protected by password and accessible only to the persons responsible for the study (Prof. Lasalvia and collaborators).
The Promoter is committed to keeping a hard copy of the informed consent for at least 7 years in compliance with DL 200/2007. All computers in which the data will be stored, once downloaded by the person responsible for data management, will be protected by keywords. The local in which the computers are kept will be locked and protected by alarm systems if unattended. Responsible for the custody is the Principal Investigator (Prof. Antonio Lasalvia).
The study was approved on August 13th, 2024, by the Ethics Committee of the South-West Veneto Area (approval No. 358CET). All participants will be asked to provide a written informed consent to participate in the study. Prof. Antonio Lasalvia is responsible for obtaining informed consent. The trial was registered on ClinicalTrials.gov, Identifier: NCT06567145; August 20, 2024.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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References

1. Angermeyer MC, Dietrich S. Public beliefs about and attitudes towards people with mental illness: a review of population studies. Acta Psychiatr Scand. 2006;113(3):163–79.
2. Pescosolido BA, Medina TR, Martin JK, Long JS. The "backbone" of stigma: identifying the global core of public prejudice associated with mental illness. Am J Public Health. 2013;103(5):853–60.
3. Thornicroft G, Brohan E, Rose D, Sartorius N, Leese M. Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey. Lancet. 2009;373(9661):408–15.
4. Lasalvia A, Zoppei S, Van Bortel T, Bonetto C, Cristofalo D, Wahlbeck K, et al. Global pattern of experienced and anticipated discrimination reported by people with major depressive disorder: a cross-sectional survey. Lancet. 2013;381(9860):55–62.
5. Brohan E, Elgie R, Sartorius N, Thornicroft G. Self-stigma, empowerment and perceived discrimination among people with schizophrenia in 14 European countries: The GAMIAN-Europe study. Schizophr Res. 2010;122(1–3):232–8.
6. Krajewski C, Burazeri G, Brand H. Self-stigma, perceived discrimination and empowerment among people with a mental illness in six countries: Pan European stigma study. Psychiatry Res. 2013;210(3):1136–46.
7. Corrigan PW, Watson AC. The paradox of self-stigma and mental illness. Clin Psychol Sci Pract. 2002;9(1):35.
8. Stangl AL, Earnshaw VA, Logie CH, van Brakel W, C Simbayi L, Barré I, et al. The Health Stigma and Discrimination Framework: a global, crosscutting framework to inform research, intervention development, and policy on health-related stigmas. BMC Medicine. 2019;17(1):31.
9. West ML, Yanos PT, Smith SM, Roe D, Lysaker PH. Prevalence of internalized stigma among persons with severe mental illness. Stigma Res Action. 2011;1(1):3–10.
10. Livingston JD, Boyd JE. Correlates and consequences of internalized stigma for people living with mental illness: A systematic review and meta-analysis. Soc Sci Med. 2010;71(12):2150–61.
11. Dubreucq J, Plasse J, Franck N. Self-stigma in serious mental illness: A systematic review of frequency, correlates, and consequences. Schizophr Bull. 2021;47(5):1261–87.
12. Yanos PT, Roe D, Lysaker PH. The impact of illness identity on recovery from severe mental illness. Am J Psychiatric Rehabil. 2010;13(2):73–93.
13. Yanos PT, Roe D, Markus K, Lysaker PH. Pathways between internalized stigma and outcomes related to recovery in schizophrenia spectrum disorders. Psychiatr Serv. 2008;59(12):1437–42.
14. Cavelti M, Rüsch N, Vauth R. Is living with psychosis demoralizing?: Insight, self-stigma, and clinical outcome among people with schizophrenia across 1 year. J Nerv Mental Dis. 2014;202(7):521–9.

15. Yanos PT, DeLuca JS, Roe D, Lysaker PH. The impact of illness identity on recovery from severe mental illness: A review of the evidence. Psychiatry Res. 2020;288:112950.
16. Yanos PT, Roe D, West ML, Smith SM, Lysaker PH. Group-based treatment for internalized stigma among persons with severe mental illness: findings from a randomized controlled trial. Psychol Serv. 2012;9(3):248.
17. Roe D, Hasson-Ohayon I, Mashiach-Eizenberg M, Derhy O, Lysaker PH, Yanos PT. Narrative enhancement and cognitive therapy (NECT) effectiveness: A quasi-experimental study. J Clin Psychol. 2014;70(4):303–12.
18. Hansson L, Lexén A, Holmén J. The effectiveness of narrative enhancement and cognitive therapy: a randomized controlled study of a self-stigma intervention. Soc Psychiatry Psychiatr Epidemiol. 2017;52:1415–23.
19. Yanos PT, Lysaker PH, Silverstein SM, Vayshenker B, Gonzales L, West ML, et al. A randomized-controlled trial of treatment for self-stigma among persons diagnosed with schizophrenia-spectrum disorders. Soc Psychiatry Psychiatr Epidemiol. 2019;54:1363–78.
20. Huang LT, Liu CY, Yang CY. Narrative enhancement and cognitive therapy for perceived stigma of chronic schizophrenia: A multicenter randomized controlled trial study. Arch Psychiatr Nurs. 2023;44:59–68.
21. Barlati S, Morena D, Nibbio G, Cacciani P, Corsini P, Mosca A, et al. Internalized stigma among people with schizophrenia: Relationship with sociodemographic, clinical and medication-related features. Schizophr Res. 2022;243:364–71.
22. Rossi A, Galderisi S, Rocca P, Bertolino A, Mucci A, Rucci P, et al. The relationships of personal resources with symptom severity and psychosocial functioning in persons with schizophrenia: results from the Italian Network for Research on Psychoses study. Eur Arch Psychiatry Clin Neurosci. 2017;267:285–94.
23. Rossi A, Galderisi S, Rocca P, Bertolino A, Rucci P, Gibertoni D, et al. Personal resources and depression in schizophrenia: the role of self-esteem, resilience and internalized stigma. Psychiatry Res. 2017;256:359–64.
24. Lanfredi M, Zoppei S, Ferrari C, Bonetto C, Van Bortel T, Thornicroft G, et al. Self-stigma as a mediator between social capital and empowerment among people with major depressive disorder in Europe: The ASPEN study. Eur Psychiatry. 2015;30(1):58–64.
25. Lasalvia A. Lo stigma dei disturbi mentali. Guida agli interventi basati sulle evidenze Roma: Giovanni Fioriti Editore. 2022;
26. Yanos PT, Roe D, Lysaker P. Rinforzo Narrativo e Terapia Cognitiva per l'auto-stigma. Come lo sviluppo di una nuova narrazione di sé e la riformulazione di pensieri disfunzionali può contrastare l'auto-stigma nelle persone con malattia mentale. Italian version by Lasalvia A, Bodini L, Bonetto C. Roma: Fioriti Editore; 2024. 1–57 p.
27. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 Statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200–7.
28. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide BMJ 2014; 348: g1687.
29. Corrao G, Barbato A, D'Avanzo B, Di Fiandra T, Ferrara L, Gaddini A, et al. Does the mental health system provide effective coverage to people with schizophrenic disorder? A self-controlled case series study in Italy. Soc Psychiatry Psychiatr Epidemiol. 2022;57(3):519–29.
30. Lora A, Starace F, Di Munzio W, Fioritti A. Italian community psychiatry in practice: description and comparison of three regional systems. J Nerv Mental Dis. 2014;202(6):446–50.
31. Lora A, Monzani E, Ibrahim B, Soranna D, Corrao G. Routine quality care assessment of schizophrenic disorders using information systems. Int J Qual Health Care. 2016;28(6):728–33.
32. First MB, Williams JB, Karg RS, Spitzer RL. Structured clinical interview for DSM-5 disorders: SCID-5-CV clinician version. DC: American Psychiatric Association Publishing Washington; 2016.
33. Ritsher JB, Otilingam PG, Grajales M. Internalized stigma of mental illness: psychometric properties of a new measure. Psychiatry Res. 2003;121(1):31–49.
34. Boyd JE, Adler EP, Otilingam PG, Peters T. Internalized Stigma of Mental Illness (ISMI) scale: a multinational review. Compr Psychiatry. 2014;55(1):221–31.
35. Rosenberg M. Society and the adolescent self-image. Princeton University. 1965.
36. Crandal R. The measurement of self-esteem and related constructs. In: Robinson JP, Shaver PR, editors. Measures of social psychological attitudes. Revised. Ann Arbor: ISR; 1973. p. 80–2.
37. Sinclair SJ, Blais MA, Gansler DA, Sandberg E, Bistis K, LoCicero A. Psychometric properties of the Rosenberg Self-Esteem Scale: Overall and across demographic groups living within the United States. Eval Health Prof. 2010;33(1):56–80.
38. Beck AT, Weissman A, Lester D, Trexler L. The measurement of pessimism: the hopelessness scale. J Consult Clin Psychol. 1974;42(6):861.
39. Balsamo M, Carlucci L, Innamorati M, Lester D, Pompili M. Further insights into the beck hopelessness scale (BHS): Unidimensionality among psychiatric inpatients. Front Psych. 2020;11:727.
40. Rogers ES, Chamberlin J, Ellison ML. Measure empowerment among users of mental health services. Psychiatr Serv. 1997;48(8):1042–7.
41. Straticò E, Mirabella F. Proprietà psicometriche della SESM, versione italiana della Scala degli utenti per misurare l'Empowerment nei servizi di Salute Mentale (Roger set al., 1997) [in Italian]. Epidemiology and Psychiatric Sciences. 2007;16(3).
42. Corrigan PW, Salzer M, Ralph RO, Sangster Y, Keck L. Examining the factor structure of the recovery assessment scale. Schizophr Bull. 2004;30(4):1035–41.
43. Boggian I, Lamonaca D, Ghisi M, Bottesi G, Svettini A, Basso L, et al. "The Italian study on recovery 2" phase 1: psychometric properties of the recovery assessment scale (RAS), Italian validation of the recovery assessment scale. Front Psych. 2020;10:1000.
44. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. Health Qual Life Outcomes. 2007;5(1):63.
45. Rüsch N, Corrigan PW, Wassel A, Michaels P, Olschewski M, Wilkniss S, et al. A stress-coping model of mental illness stigma: I. Predictors of cognitive stress appraisal. Schizophrenia Research. 2009;110(1–3):59–64.
46. Oudejans S, De Winter L, Van Weeghel J, Sanches S, Hasson-Ohayon I. Feasibility and outcomes of narrative enhancement and cognitive therapy (NECT) for reducing self-stigma among people with severe mental illness in the Netherlands: A pilot study. Psychiatr Rehabil J. 2022;45(3):255.
47. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. J Clin Epidemiol. 1999;52(1):19–26.

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