Patient Capacity and Dynamic Aspects of the Psychotherapeutic Process Impacting the Course and Outcomes of Treatment

Short Title:

Dynamics of Psychotherapy and Treatment Outcomes

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1. Introduction

Psychotherapy outcomes are influenced by dynamic, ongoing factors within the therapeutic relationship. Understanding how traits like mindfulness, resilience, and insight — as well as therapeutic alliance — affect the process can guide more effective treatments. This study aims to track these dynamic factors and their association with changes in neurotic symptoms over a 12-week group therapy program.

2. Objectives

Primary Objective:

To investigate the association between dynamic aspects of the psychotherapeutic process — such as therapeutic alliance, insight, and mindfulness — and treatment outcomes, particularly the reduction of neurotic symptoms and the enhancement of resilience.

Secondary Objectives:

To conduct multiple analyses based on the collected data, including but not limited to the following planned studies:

- "Trait-like and State-like Components of Therapeutic Alliance and Insight Influencing Psychotherapy Outcomes in Group Dynamic Psychotherapy."
- " Pathways of Change in Psychotherapy: The Role of Insight, Alliance, and Mindfulness in Building Resilience”

3. Study Design

Type: Interventional
Primary Purpose: Treatment
Model: Single Group Assignment
Masking: None (Open Label)
Allocation: Non-Randomized
Duration: 12 weeks
Participants undergo group psychotherapy focused on monitoring and enhancing therapeutic alliance, mindfulness and insight development. Assessments occur at four points: week 1, week 4, week 8, and week 12.

4. Study Population

Inclusion Criteria:

- Diagnosis of neurotic disorders (ICD-10: F40–F48.9) or mild to moderate personality disorders (ICD-10: F60–F61).
- Age ≥18 years.
- Ability to provide informed consent.

Exclusion Criteria:

- Diagnosis of psychotic and/or organic mental disorders.
- Active substance addiction.

Sample Size: 89 participants enrolled.

5. Methods

Participants will participate in a manualized group dynamic psychotherapy conducted at the Psychotherapy Unit, University Hospital in Krakow. During the 12-week intervention, participants will complete a battery of questionnaires at four designated time points.

Assessment Tools:

1) Resilience Level Assessed by the Connor-Davidson Resilience Scale Short Version (CD-RISC-10)

Connor-Davidson Resilience Scale Short Version (CD-RISC-10) is a 10-item scale used to assess resilience, defined as the ability to cope with stress in response to challenging experiences. The full CD-RISC consists of 25 items and has a five-factor structure, both versions displaying sound psychometric properties. Observations made during the development of the original scale indicate that resilience can be modified and improved through appropriate interventions, and greater improvement in resilience scores corresponds to more significant overall treatment outcomes. CD-RISC is one of the most frequently used tools to measure resilience. This study employed the short version, CD-RISC-10, which includes two factors labeled as Endurance and Perseverance. The CD-RISC-10 uses a 5-point Likert scale to assess resilience.

2) Neurotic Symptoms Questionnaire "O" (SQ-O)

The Symptoms Questionnaire "O" (SQ-O), a validated 187-item self-report tool used to measure the severity of neurotic symptoms across affective, somatic, and behavioral domains. The checklist includes 14 subscales covering different areas of neurotic psychopathology. The SQ-O can be used both diagnostically, to assess the overall severity of symptoms (cut-off scores are sex-adjusted; scores above 165 for men and 200 for women indicate symptoms exceeding the norm), as well as a measure of treatment-related change. This study focused on the overall scale scores measured at specified time points, without analyzing changes in individual subscales. Each item is scored dichotomously (0 = no, 1 = yes).

3) Psychological Insight Assessed by the Psychological Insight Questionnaire (PIQ)

Psychological Insight Questionnaire (PIQ) is a tool used to assess insight, defined as a series of realizations and discoveries related to personality, relationships, behavioral patterns, and emotions. The questionnaire consists of 23 items rated on a 6-point Likert scale (from 0 - none/not at all to 5 - extreme) to indicate the intensity of each experienced state over the last 7 days. The scale includes two subscales: (1) Avoidance and Maladaptive Patterns Insights and (2) Goals and Adaptive Patterns Insights, both of which demonstrate satisfactory internal consistency (Cronbach's α = 0.93 and 0.85, respectively). Although initially developed to explore the acute and lasting effects of psychedelic use, the content, sound psychometric properties, and simplicity of the PIQ encourage its use in other areas where psychological insight may be critical in predicting psychotherapy outcomes.

4) Therapeutic Alliance Level Assessed by the Working Alliance Inventory - Short Revised (WAI-SR)

Working Alliance Inventory - Short Revised (WAI-SR) is a 12-item revised measure assessing the quality of the therapeutic alliance as perceived by the patient. Extensive research has confirmed its effectiveness in predicting treatment outcomes. Most researchers recommend using the overall score, as the two identified subscales - Goal/Task and Bond - strongly correlate, which could interfere with accurate interpretation. The WAI-SR uses a 5-point Likert scale to assess the strength of the therapeutic alliance.

5) Freiburg Mindfulness Inventory - Short Form (FIU-14)

The Freiburg Mindfulness Inventory - Short Form (FIU-14) is a 14-item self-report scale designed to measure mindfulness as a general psychological trait. Mindfulness is described as a personal trait of being mindful of the moment-by-moment experience. Some of the features of mindfulness include openness, receptiveness, curiosity, and a nonjudgmental attitude. It assumes that an open and attentive individual is more in touch with feelings and experiences. Fourteen items of the questionnaire define mindfulness as a process of regulating attention. The items are rated on a 4-point Likert scale, from 1 = "rarely" to 4 = "almost always". The reliability measure of this short version is acceptable (Cronbach's alpha between 0.79 and 0.86).

6. Outcome Measures

Primary Outcomes:

- Changes in neurotic symptoms measured by the "O" Symptom Questionnaire.
- Changes in resilience measured by CD-RISC-SV.

Secondary Outcomes:

- Changes in therapeutic alliance (WAI-SR scores).
- Changes in psychological insight (PIQ scores).
- Changes in mindfulness (FMI scores).

7. Statistical Analysis

Descriptive statistics will be calculated for all baseline variables.

Longitudinal changes will be analyzed using:

- Correlation analyses between changes in process variables (alliance, insight, mindfulness) and clinical outcomes (symptom reduction, resilience)
- Repeated Measures ANOVA
- Mixed-Effects Models (Random and Fixed Effects)

Missing data will be handled using multiple imputation methods. A significance level of $\alpha = 0.05$ will be used for all inferential analyses.

8. Ethical Considerations

The study has been reviewed and approved by the Bioethics Committee of the Jagiellonian University Medical College (Approval Number: 1072.6120.189.2022). Participation is voluntary, and participants can withdraw at any time without affecting their ongoing treatment. All participants will provide written informed consent prior to enrollment.

9. Data Management and Confidentiality

Data will be pseudonymized and stored on secure institutional servers at the University Hospital in Krakow. Access to identifiable data will be limited to authorized personnel only. Data will be retained for a minimum of five years after study completion.

10. References

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11. Appendices

Appendix A: Informed Consent Form for Study Participation (English Version)

Appendix A

INFORMED CONSENT FORM FOR STUDY PARTICIPATION

I hereby declare that:

1. I have read the Participant Information Sheet, of which I have received one copy.
2. I have been informed by the person recruiting participants about the purpose of the study entitled *" Patient Capacity and Dynamic Aspects of the Psychotherapeutic Process Impacting the Course and Outcomes of Treatment".*
3. The recruiting person has thoroughly explained to me the procedure of the study, in accordance with the description provided in the Participant Information Sheet.
4. I have had the opportunity to ask questions and have received satisfactory answers to all my inquiries.
5. I understand the nature of the study, to which I have been invited, and I understand that it involves completing questionnaires.
6. I understand the risks and benefits associated with my participation in the study.
7. I understand that my participation in the study is voluntary and that I may refuse to participate or withdraw from it at any time without providing any reason.
8. I am aware that my withdrawal will not affect my further treatment in any way.

In view of the above, I hereby give my informed and voluntary consent to:

1. participate in the study entitled "Dynamic Aspects of the Psychotherapeutic Process Affecting the Course and Outcomes of Treatment";
2. the processing of my data, including data concerning my health, contained in the medical documentation of the hospital – the Psychotherapy Department of the University Hospital – and collected during the study (questionnaires), to the extent necessary for the realization of the study, with the reservation that the confidentiality of my personal information will be maintained;
3. the use of my data in an anonymous form for the preparation of scientific publications and presentations.

I confirm that I have received one copy of this document.

…….. Name and surname of the person recruiting participants for the study	…….. Name and surname of the study participant
…….. Place and date …….. Signature of the person recruiting participants for the study	…….. Place and date …….. Signature of the study participant