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The Psychotherapeutic Process: From Scientific Research to Treatment Evaluation

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ABSTRACT

The psychotherapeutic process is a path of change guided by a psychotherapist, who helps to modify dysfunc-tional thoughts, emotions and behaviours to reduce psychological suffering, resolve negative mental patterns, improve psychological well-being and promote a more functional adaptation to life. This process is so complex that its evolution is unpredictable: even minimal variations in the initial conditions produce effects which can be very significant and are not deterministically connected to the conditions themselves. For this reason, it is essential to verify the effectiveness of the treatment through an evidence-based approach: return and/or reduc-tion of symptoms compared to the baseline and maintenance of the same, transformation of the variables typ-ical of a particular disorder (depression, OCD, etc.) and of the peculiarities of that particular subject, and the progress of the relationship that this transformation produces and sustains over time.

Therefore, to have an accurate representation of the process of change, it is necessary to have an assessment tool that can detect useful indicators significant for improving the therapist-patient relationship and treatment outcome throughout the duration of therapy.

One tool that seems to meet these characteristics, although still statistically insignificant, is the Psychotherapy Evaluation Questionnaire (PEQ) designed and developed by one of the authors (G.M.G.), which allows the ef-fectiveness of therapy to be investigated by examining the following areas: 1) Therapeutic relationship, 2) Mo-tivation for therapy, 3) Adherence to therapy, and 4) Outcomes.

Keywords

Psychotherapeutic process, Scientific research in psychotherapy, Evaluation of psychotherapy, Therapist-patient relationship.

Introduction

The psychotherapeutic process is a journey of change guided by a psychotherapist, who helps to modify dysfunctional thoughts, emotions and behaviours to reduce psychological suffering, resolve negative mental patterns, improve psychological well-being and promote a more functional adaptation to life. It is divided into distinct phases:

1. ***Initial assessment (anamnesis):*** The patient contacts the therapist to explore the nature of their distress, and through interviews, tests and questionnaires, a diagnosis is made, and goals are set.
2. ***Treatment*:** In this phase, the therapist, based on the chosen approach (e.g., cognitive-behavioural, systemic-relational, etc.), guides the patient to: understand the mechanisms underlying thoughts, attitudes, and symptoms; modify dysfunctional patterns (intervene on problematic thought patterns or behaviours, promoting more effective solutions); develop coping strategies (learning new strategies for dealing with difficulties, in harmony with oneself and one's environment); and tackle the process "beyond the session" (psychotherapeutic work continues outside the session, with home working exercises, practising new ways of thinking and acting).
3. ***Consolidation and conclusion*:** This occurs when the patient can manage critical situations and has achieved the agreed objectives. Sessions are gradually spaced out to consolidate progress and support the maintenance of results.

These phases summarise the process of conceptualisation and case formulation, in which: conceptualisation is the process of understanding and interpreting the patient's problems through the integration of assessment data, while formulation is a subsequent and more focused phase that applies a theoretical model to describe the issues, their causes and maintenance factors to direct therapy effectively. In other words, conceptualisation provides the basic understanding, while formulation uses this understanding to create a specific model that guides the therapeutic intervention [1].

The essential problem that emerges from the three previous stages is the need to address the complexity of the psychotherapeutic process and its development over time: that is, it must focus on the intervention, respond to multiple, indivisible problems and, at the same time, attempt to understand the set of behaviours on which it is necessary to work; for example, to evaluate the progress and outcomes of psychotherapy. To assess the latter, it may be useful to gather information (through an interview at the end of treatment) on what happened during treatment (with regard to variables such as the relationship with the therapist, the feeling of effectiveness of the therapy, satisfaction with expectations, etc.) and consider the objectives that were identified when the clinical project was formulated: remission (total or partial of symptoms), modification of certain aspects of personality functioning, partial or total resolution of any key issues, acquisition of better coping strategies, an increase in subjective well-being, an increase in social skills and the prevention of "crises" or the recurrence of symptoms.

These aspects of the assessment lead us to ask the question: "Does psychotherapy meet the scientific criteria of other scientific disciplines?". We will attempt to answer this question in the following paragraphs, starting with the historical and cultural development of research in psychotherapy.

Scientific Research in Psychotherapy

Scientific research is an activity aimed at discovering and interpreting facts, events and theories relating to any field of human knowledge and experience, based essentially on the scientific experimental method (which is based on initial observation, followed by an experiment, developed in a controlled manner, so that the phenomenon to be studied can be reproduced. The experiment aims to validate or refute the hypothesis formulated by the scientist, which seeks to explain the mechanisms underlying that event. Scientific research also serves to increase knowledge in the field of science and is considered one of the key factors in achieving technical and scientific development. It is divided into [2]:

- *basic research* (pure or fundamental research), whose primary objective is the advancement of knowledge and theoretical understanding of the relationships between the different variables involved in each process. It is conducted without any practical purpose in mind, although its results may have unexpected applications. The term "basic" implies that research generates new theories, laying the groundwork for further studies with medium- to long-term applications.
- *Applied research* is carried out with the aim of finding practical and specific solutions. Its primary objective is not the advancement of theoretical knowledge, but rather the exploitation of already acquired theoretical knowledge for practical purposes, i.e. essentially for technical and technological development.
- *Theoretical and experimental research*: in certain fields, such as physics and earth sciences, a distinction is made between *theoretical research*, which develops theoretical-interpretative models of physical phenomena (in the form of physical theories), and *experimental research*, which observes the results of theoretical research and experimentally confirms previously formulated physical theories.
- *Clinical research* is an experimental procedure in the health and pharmaceutical fields, aimed at confirming the validity of medical interventions designed to improve therapeutic response.

In this context, despite differences in the conditions of use of methods and techniques, scientific research on psychotherapy also falls within this scope. Without compromising the rigour of the scientific method, it aims not only to increase knowledge and verify theoretical hypotheses, but also to modify the object of study of psychotherapy through experimental treatment [3].

The historical development of scientific research on psychotherapy

To examine the evolution of scientific research on psychotherapy, a detailed account of its development over the last few decades would be necessary, but for the sake of brevity, some aspects will be outlined (the division into selected periods is arbitrary and serves only to contextualise certain events), highlighting only a few fundamental passages characterised by specific historical and psychological moments [4-6]:

- 1950s-1969

During these years, the debate was dominated mainly by attempts to respond to an article by Eysenck [7], who had argued that there was no evidence of the effectiveness of any psychotherapy (in reality, the reference was mainly to psychoanalysis) and that improvement was due to so-called "spontaneous remission", i.e. the passage of time. Unlike pharmacological research, it is not possible to conduct strictly controlled "double-blind" studies (in which both the subjects and the experimenters are unaware of important information that could significantly influence the results) in psychotherapy. Furthermore, one of the most frequent (and pertinent) criticisms levelled by clinicians at researchers concerns the fact that, while research considers patients with "pure" diagnoses to reduce the number of variables to be considered, in clinical reality, most patients present with comorbid conditions.

For all these reasons, the typical experimental situation in psychotherapy research is not represented by a treated group compared with an untreated control group, but by the comparison of two different types of psychological intervention with each other [8]. During the last years of this period, there was also a rapid and convulsive explosion of psychotherapy research "manuals"[1] which,

1 In which the following were taken into consideration: 1) the selection

due to their characteristics, significantly improved the quality of research methodology, as they made it possible to measure the concordance between a given manual and the psychotherapeutic technique tested.

- 1970s-1984

Despite various experimental attempts during the first decade, without achieving a significant breakthrough, in the early 1980s, Smith, Glass and Miller [9] and Shapiro and Shapiro [10] introduced a new technique called "meta-analysis"[2], with which they analysed a total of 597 controlled studies on the results of psychotherapy. This research revealed that there was spontaneous remission in some untreated control groups and improvement in many patients treated with "placebo", but it also showed that psychotherapies, on average, achieve significantly better results than both untreated controls and "placebo", and that these results tend to be long-lasting [11]. Although these results demonstrated the effectiveness of psychotherapy, they failed to demonstrate the superiority of one psychotherapeutic technique over another, thus forcing researchers to accept the "paradox of equivalence". This paradox asserts that although different therapeutic approaches are based on different conceptual models of psychopathology and the healing process, they are equivalent in terms of results and that the study of the results was not sufficient to understand how psychotherapy works. It was therefore necessary to study the process to investigate the therapeutic "microprocesses" and better understand the phenomena that are perceived clinically as macro processes [12,13].

- 1985s-1999

The process-oriented approach, while giving new impetus to research on common factors, implicitly represented a symbol of fierce controversy over the privilege of specific approaches for specific pathologies based on RCTs (randomised controlled trials). This position, which arose within the medicalised model of psychotherapy (EBM) [86] and which led to the *Empirically Supported Treatments*[3] (ESTs) movement, assumed that each therapy model had different effects on different disorders, leading to the inference that some models were more effective than others with certain types of patients. Furthermore, during these years, a manifestation emerged in various forms within internal debates, which has only been resolved in recent years. One of these ways was the conflict between those who believed that therapy should be practised according to the indications of empirically validated treatments and those who, on the contrary, considered such indications useless because they did not meet the concrete needs of clinicians in real situations. However, through an increasingly conspicuous and adequate dialogue between the world of research and that of clinical practice, impetus was given to the realisation of an increasing number of studies under "naturalistic observation" conditions, questioning the principle that only randomised studies, in which the conditions for the inclusion of subjects were highly controlled and selected, could constitute the only possibility for determining the effectiveness of a treatment.

Overall, it can be said that during this period, research in psychotherapy has become more established, with many working groups in various countries, many prejudices about its usefulness have been overcome, and an increasing number of researchers have broken the ties that bound them to their respective schools to find themselves in cross-disciplinary alliances [20-22].

- 2000s – Today

As with other disciplines, scientific research in psychotherapy has also been influenced by neuroscience, which utilises neuroimaging to identify the areas of the brain where certain thoughts or emotions are formed, on the assumption that understanding how the brain works during psychotherapy will resolve issues related to its effectiveness.

In this dialogue (between psychotherapy and neurobiology), different and divergent attitudes emerged: from radical antagonism to scepticism, from indifference to enthusiastic support for a future "neuro-psychotherapy" and the possibility of monitoring the psychotherapy process with neuroimaging methods [23,24]. Studies on brain changes caused by psychotherapy are still preliminary and speculative and require further experimental confirmation. Psychotherapy, in fact, like psychopharmacology, works simultaneously by changing minds (subjectivity) and neural networks (objectivity) and this, perhaps in a relatively short time, could change and improve the neurobiological models useful for the design, implementation and verification of the outcomes of psychotherapeutic intervention [25,26].

of the principles of a particular psychotherapy technique, 2) practical examples of each principle, and 3) the presence of rating scales that measure the degree to which a therapy subject falls within the principles of that technique; for example, Wolpe's manual [14] for behavioural therapy and Beck, Rush, Shaw & Emery's manual [15] for cognitive therapy for depression.

2 Meta-analysis is a technique that analyses multiple clinical studies that have provided conflicting results on the same treatment. The aim is to provide a clear and conclusive result on therapeutic efficacy. Just as a clinical trial studies a group of patients (sample), meta-analysis studies a group of clinical trials, using a protocol that collects the common aspects of the individual protocols. Various techniques and statistical tests are then used to process the numerical results of the individual studies to obtain a final cumulative parameter (the so-called "overall odds ratio") [16].

3 The importance of identifying psychotherapies supported by empirical evidence was formalised in 1995, when the Task Force on Promotion and Dissemination of Psychological Procedures of Division 12 (Clinical Psychology) of the American Psychological Association (APA) identified a number of psychological interventions considered reliable (later referred to as Empirically Supported Treatments (ESTs) or Empirically Validated Treatments (EVTs) [17,18]. ESTs were inspired by Evidence-Based Medicine (EBM) [86] and were based on randomised controlled trials (RCTs) [18,19]. In a 1995 report, the Task Force outlined the criteria for selecting an EST and reported a preliminary list of selected treatments [17]. For a treatment to be indicated as likely to be effective, it had to be shown to be superior to a non-treatment condition (e.g., placebo or waiting list condition). The basic assumption of ESTs was, in principle, that there was an objective and measurable reality and that reliable conclusions could be reached through scientific methodologies: the procedure for symptom improvement was thus characterised by diagnosis and treatment prescription.

Knowing, for example, that the level of activity in the anterior cingulate gyrus of depressed patients predicts their subsequent response to selective serotonin reuptake inhibitor treatment, having a more complete picture of the biological substrates underlying mental disorders, for example, could contribute to the choice of the type of psychotherapy to be applied and to knowing whether, in treating the after-effects of psychological trauma, there are permanent changes not only in psychological functioning but also in brain structures [27-29]. The dialogue between neuroscience and psychotherapy, therefore, could be fruitful not only on a conceptual level but also on a practical level. However, it would be an illusion to expect that the complex interpersonal processes and subtleties of the interaction between patient and therapist that occur during psychotherapy could ever be fully described in neurobiological terms [30-32].

The neuroscientific study of the psychotherapeutic process has therefore highlighted how verbal and non-verbal aspects mediate a therapeutic effect through neuronal changes, producing an increasingly broad consensus in favour of a bio-psycho-social approach [33]. Such research has required the collection of psychophysiological measurements before and after, and sometimes during, treatment, which has further complicated the issue of detection devices that potentially alter the process: audio or video recording of sessions, for example, by introducing a foreign element into the setting, can compromise the relationship of trust between patient and therapist [29,34,35]. This aspect must be taken into serious consideration by the researcher, both from an epistemological point of view (observation alters the phenomenon being observed) and a methodological point of view (when analysing the results of their research), but above all from an ethical and deontological point of view. This does not imply giving up research, but it does require a more careful evaluation and an informed choice of methodologies to be adopted, focusing on compatibility with clinical needs and consistency with the study's aims, while also determining which outcome aspects are to be investigated [34].

As can be seen from this brief historical overview of scientific research in psychotherapy, it is challenging to take stock due to the subject's complexity and the various interpretations that can be attributed to it. A first consideration, however, is that empirical research, having to address common problems, has managed to break down barriers and form cross-disciplinary alliances between schools, thanks also to the changes that have already occurred and those that are rapidly emerging within individual theoretical paradigms. All this, however, is not enough to bring psychotherapy out of its pre-scientific state and into the state of "normal science"[4] referred to by Kuhn [36], even though research using collected data is becoming increasingly relevant to practice.

Methodological considerations on scientific research in psychotherapy

Scientific studies in psychotherapy refer to rigorous experimental research, even in the absence of evidence of the effectiveness of the treatment under investigation, excluding those with a methodology that is not considered suitable. In general, a research practice is considered scientific if it is open to intersubjective control, has clear definitions of concepts and postulates, employs readable and repeatable procedures, and utilises an experimental method for validating hypotheses. Psychotherapy as a science should therefore be based on the following epistemological assumptions [37]: 1) the psychotherapeutic process is an action aimed at behavioural change (covert and/or overt) that creates suffering and/or maladjustment, with specific objectives determined by the therapist's theoretical model of reference; 2) the objectives are pursued in each theoretical model using specific techniques (legible and repeatable from the outside in order to ensure the intersubjectivity of control); 3) change occurs within a relationship between "subjects" (therapists/clients) whose dimensions can be assessed and explained in both theoretical and real terms.

With regard to the method for validating hypotheses, the scientific approach follows three main modes: logical validation (checking the consistency between the new knowledge generated by the hypotheses and the body of knowledge present in the same theory or field of research and evaluating the congruence between the theory on the pathology, the treatment objectives and the strategies actually used), pragmatic empirical validation (ascertaining, through a series of data derived from experiences in which the variables are kept under control as much as possible, whether and to what extent the hypotheses "work" and are useful for the proposed purpose: ascertaining whether a "therapeutic intervention" actually reduces symptoms and produces better adaptation in the subject) and explanatory empirical validation (verifying hypotheses aimed at explaining, again through research that controls the variables involved, why a certain process works).

When conducting research on psychotherapy, it is therefore necessary to consider three types of "effect" that can be investigated [38]:

• ***Efficacy*****:** the effectiveness determined by a clinical experiment in which a large number of variables are controlled to demonstrate that the relationship between treatment and outcome is relatively certain; in this type of study, internal validity (the degree to which it is possible to infer a causal relationship between variables) is emphasised through: control of the types of patients to be included in the research, the use of manuals to standardise the delivery of treatments, preliminary training of therapists, monitoring of adherence to the manual, randomised assignment to treatment/control groups.

4 In his work 'The Structure of Scientific Revolutions' [38], Kuhn argues that the historical development of science took place through the contrast between periods of 'normal science', characterised above all by the attempt of the scientific community to recognise itself within a given set of theories (the paradigm), and periods of 'extraordinary science' (in which new events can falsify some of these theories, gradually undermining the dominant paradigm), characterised by insights that may also be of an extra-scientific nature and, in any case, by freer research patterns. In this way, new hypothetical paradigms can come into "conflict" until the scientific community converts to a new paradigm that has greater explanatory weight than the one abandoned. Thus, a new period of "normal" science begins and the cycle closes.

• ***Effectiveness*****:** the effectiveness of psychotherapy in real clinical contexts, with an emphasis on external validity, relative to the context, to demonstrate that the treatment can be useful in a natural clinical setting; this type of study includes naturalistic observational studies and the analysis of single cases, which may be selected at random.
• ***Efficiency*****:** the assessment of the cost-benefit ratio of a treatment.

The nomothetic and quantitative demonstration of the effectiveness of a treatment cannot be considered the only way to verify how much the subject's symptoms and mental functioning change as a result of treatment (return and/or reduction of symptoms compared to baseline and maintenance of the same), but it is also necessary to refer to a qualitative approach to follow the transformation of both the variables typical of a particular pathology (depression, OCD, etc.) and the peculiarities of that particular subject, as well as the progress of the relationship that this transformation produces and sustains over time. The treatment is so complex that its evolution is unpredictable: minimal variations in the initial conditions produce effects, even very significant ones, that are not deterministically connected to the conditions themselves (a development that is defined as "chaotic" precisely because of its unpredictability). These theories have challenged traditional conceptions of science (only what can be quantitatively verified can constitute scientific work), laying the foundations for a new epistemology in which the reformulation of the universe of knowledge makes use of both non-experimental methodologies (e.g. observational, but with standardised criteria that can be shared by other scholars) and empirical data, not necessarily limited to objective aspects, which may also concern subjective data, provided that they are translated into indicators that can be analysed using reliable techniques such as traditional statistics [39].

At this point, hypothesising the construction of a clinically correct model, theory and practice may mean, in the first instance, satisfying the need to question contemporary epistemology and, in the second instance, overcoming the dichotomies (quantitative methods vs. qualitative methods, experimental methods vs. non-experimental methods, etc.), which are so abused in psychology, in favour of an integration of different points of view that takes into account the advantages offered by each. This is done in the belief that attention should always be paid to all the "variables at play", even when they are extraordinarily complex, perhaps contrary to expectations. It is precisely the concept of complexity, or rather the epistemology of complexity, that is playing a particularly important role in the sciences, highlighting a new alliance with philosophy (overcoming the presumed exhaustiveness of its theoretical models and "alliance" between the perspectives that contribute to the construction of a general discourse on complexity and knowledge), a new way of doing science (bottom-up, i.e. "from the bottom up", more in line with the way a system is organised in nature) and a new conception of natural evolution (abandoning the idea that progress governs the history of life) [40,41].

Adopting this perspective means abandoning the objectivism of classical science, i.e., viewing it as a set of manipulable and measurable objects, and taking a relational and dialogical point of view towards human beings. In summary, the complexity of a system can be defined as the minimum length of its scientific description, obviously carried out by a human observer. In fact, all complex systems have certain characteristics in common: 1) they are made up of several more or less complex components (in general, the more numerous and complex the subsystems that compose it, the more complex the system as a whole); 2) these components interact by passing information to each other, but the information they exchange cannot be too numerous (otherwise the system becomes chaotic) or too few (the system "crystallises"); 3) if there is a leading component that alone governs the behaviour of the whole, the system is not complex; 4) the more factors that influence its adaptation to the environment (learning, interaction with the observer of the system, cooperation, communication, etc.), the more complex the system is.

All human systems are in a state of unstable equilibrium, both among themselves and with the environment, and during the evolution of the system, three situations may arise: a) the system reaches a point (attractor) from which, despite any external disturbances, it no longer deviates (state of order), b) the system moves irregularly and is always unstable in the space of states (state of chaos), and c) the system converges towards certain points (attractors), but any disturbances can destabilise it (state of "edge of chaos") [42,43].

The "edge of chaos" is the state of optimal equilibrium that makes self-organisation (spontaneous organisation of the components of the system) possible. When a complex adaptive system self-organises, new and unpredictable phenomena emerge, called "emergent phenomena"[5]. With the "discovery" of complexity, therefore, the myths of certainty, completeness of knowledge and the non-existence of anything that was not quantifiable and formalizable began to crumble [42].

Scientific research proceeds by attempting to simplify complex phenomena to study them more effectively. This intent can only be pursued through methodology (understood as the set of principles, procedures, and methods that govern it) and experimental design (the general structure of the methodological action plan) used to analyse the phenomenon under study. In other words, methodology enables us to identify the possible relationships between the different variables, causes, effects, and conclusions involved in understanding certain phenomena, while experimental design indicates the various ways in which experiments can be conducted.

These ways, in addition to being pursued through the group research

5 In epistemology, a phenomenon is said to be emergent if and only if: a) it is processual in nature, b) it can be described using language that is qualitatively different from that used to describe the other properties of the system with which it is associated, c) its behaviour is not predicted by the model of the system, and d) its existence does not depend on the existence of individual components of the system. Emergent phenomena, therefore, such as learning and exploring the therapeutic relationship, are the same phenomena that make existence possible and make it exactly as we know it.

model, which, while demonstrating their effectiveness in isolating cause-and-effect relationships in many areas of psychology, have not found satisfactory answers in others, particularly clinical ones [44-51], have been pursued (since the 1960s with the development of a methodology called "experimental designs for single-case studies" or, in other terms, "N=1 research", "single case", etc.; [44,52], with single-case research models.

The single-case study

As can be inferred from the previous paragraphs, the aims pursued by any experimental methodology applied to the clinical universe consist in controlling: 1) the degree of efficiency and effectiveness of a treatment (outcome-oriented research), 2) the processes (strategies) used (process-oriented research), and 3) the influence exerted on the treatment by particular techniques employed (technique-oriented research) [53]. These criteria are amply satisfied by the single-case model, which provides rigorous methods for experimentation on a subject on whom numerous observations are made through operationalised measures, with the aim of assessing the relevance and quality of the changes obtained in a specific time interval established by the researcher [54].

Single-case studies have played a central role in clinical psychology, contributing significantly to the expansion of theoretical knowledge, the development of new research and the improvement of good practice, as can be seen from the work of Atkins and Sampson [55], and Nock, Michel and Photos [56], in which single-case research:

1) served as a source of hypotheses about human performance and development (e.g., learning fear in human development).
2) served to develop new intervention methods (e.g., strategies to reduce anxiety).
3) allowed the study of rare phenomena (e.g., multiple personality).
4) provided general feedback on applicability (e.g., success in treating symptomatic behaviours);
5) provided persuasive and motivational evidence (e.g., stimulation to conduct experimental research on a particular problem).

The researcher's concern, therefore, regardless of the experimental approach, is the possibility of generalising the results to different subjects and situations. This inductive process (drawing general conclusions from a limited amount of information) takes on different characteristics for experimental procedures on groups and those on single subjects. With regard to the former, reference can be made to the scientific literature [44,52,53,57-59], while for single-subject studies, the methodology used to demonstrate the generalisability of the results is that of *direct* replication (repetition of the experiment with the same characteristics as the original, but with different subjects) or *systematic* replication (repetition of the experiment with the modification or addition of a condition, e.g. environmental variables). Experimenters therefore have a series of methodological procedures at their disposal which, if applied rigorously, allow the results to be generalised even in experimental situations with a single subject [60,61].

In fact, it is possible to understand an individual's behaviour through careful monitoring of the experimental situation, without any need for statistical analysis or a large number of subjects, by following three fundamental principles: 1) prolonged observation (the baseline) of a single individual under controlled conditions, 2) the use of one or more independent variables, manipulated, however, one at a time, and 3) the elimination of the independent variable(s) and observation of the evolution of the dependent variable. In other words, behaviour is monitored in a phase prior to the "baseline" (or "phase A") and throughout the treatment period ("phase B"). This condition is necessary to assess the effect of the treatment on the subject's behaviour over time; that is, it represents a "criterion" for determining whether the intervention has produced a change in performance or behaviour or a reduction in a disorder. This assumes that the baseline, as described in note 5, has a certain stability in the observations (no increasing or decreasing trends) and that the variability (presence of "extreme" values in the observation of behaviour) tends towards 0 (although, for the latter aspect, the intervention may be aimed precisely at reducing the variability of behaviour) [61].

This paradigm (*single subject design*), which has enriched experimental research methodology with procedures that are particularly useful in monitoring the effectiveness of clinical interventions, is characterised by the operational steps described in Table 1 and the following basic principles [44,53]: repeated measurements, baseline, phase duration and reversal phases.

Psychotherapy provides a unique laboratory for this type of assessment, which can be conducted on the patient, the therapist, or variables of their interaction. From these premises, the single-case design is the preferred method of contemporary research in psychotherapy because it allows for a measurable analysis of the patient's functioning, the treatment process and the outcomes (congruence between Patient, Therapist, Treatment and Outcomes) [54,62].

The evaluation

In empirical studies in the field of psychotherapy, therefore, when we talk about outcome research, we mean research that aims to define the changes achieved through treatment, studying what happens at the end of treatment compared to the starting point (baseline[6]). The biggest problem lies in what is considered the starting point, and in fact, simply changing the outcome indicator can lead to opposite results. One of the indicators historically used to evaluate the intervention is the reduction of manifest symptoms, but such remission is not necessarily the only criterion for a

6 The baseline, which should be sufficiently extended (2-4 weeks), sufficiently stable (without positive or negative peaks) and with at least three successive measurements, indicates the measurement of behaviour before the start of a modification or teaching programme and involves measuring the difference between two conditions (comparing the effects of the intervention): the starting condition (the baseline) and the final condition (the intervention) [21].

STEPS	SUGGESTIONS
Choosing procedures	- The ideal procedure must meet the following requirements: objectivity, sensitivity, and validity; furthermore, single-case experiments place demands on the test-retest validity of the measures. - The examination procedure must be described in detail, with written guidelines to ensure that it remains consistent throughout the experiment. - The influence of repeated testing on the subject's behaviour can be minimized by prolonging the baseline measurement phase to achieve consistent performance, or by providing some pre-training sessions to familiarize the patient with the examination procedures before the actual experiment begins. - The inclusion of some tests of the target task for each examination point minimizes the effect of random variation.
Choosing an experimental design	- Any single-case experiment consists of a series of phases during which different treatments are administered or withdrawn. - The simplest experimental design is AB, where in phase A, unlike phase B, no treatment is administered. - An effect of the treatment can be recognized by the curve, which shows a very significant increase. If, on the other hand, it shows a gradual increase, this may not be distinguishable from a spontaneous recovery effect that coincides, incidentally, with the start of phase B. - A choice between more complex designs, which correspond to more rigorous methods, is necessary to pursue certain goals.
Determine the limits of the experimental phase	- The absolute lower limit for each phase is three observations: the minimum amount of information on variation and trend. - Starting a statistical analysis requires at least ten or more points for each phase, depending on the experimenter's time constraints and the subject's availability and motivation. - The decision on the duration of a phase of the experiment can be determined: at the beginning of the experiment (the experimenter defines the requirements for the end of the baseline phase, at the end of this phase he decides on the length of the subsequent phases, all phases of the experiment must be of the same length) or during the course of the experiment (i.e., the experimenter can observe variations and trends in the data from the moment they are collected, ensuring that the next phase begins at a point where the effect of the treatment has been clearly demonstrated; for example, if the data in an early phase of the baseline show a clear upward trend, the experimenter should decide to postpone the start of the first phase of treatment until the trend has been reset).
Perform a graphical analysis	- Changes in three different areas, at different stages of the experiment: 1) *data transformation* (presenting a visual description of all the information collected in a clear form and without systematic errors, with minimal data transformation and no omissions), 2) scaling (the y-axis must show the reference units, and its maximum value must be chosen so that any expected or observed measurement is clearly visible on the graph), and 3) curve fitting (interpolation curve: identify a function that passes through all data points and use it to identify new points in the collected data set).
Perform a numerical analysis	- Formulation of an experimental hypothesis that predicts how dependent variables will vary during and across different phases of the experiment. - If the graph shows a variation between phases, statistical tests for single cases must be adopted. - Repetition of the study.
Draw up a written protocol	- In the Protocol, describe in detail the experimental procedures before the experiment begins and the treatments that will be administered. - Implementation of the experiment and recording of every external event, not only on the subject's performance, but also on their health, changes in the environment, etc.

Table 1: Operational steps for monitoring the effectiveness of clinical interventions in the single-subject design paradigm, which has enriched the experimental research methodology.

"good outcome" of psychotherapy. To make a useful reference to a research protocol and its results, it is therefore necessary to consider what types of outcomes it aims to pursue and whether these aspects have been investigated with valid and relevant tools. However, the emphasis placed on symptoms and their weight in assessing the success of an intervention has increasingly diminished over time, partly because of the heated debate on the nature and meaning of symptoms in psychopathology: symptoms may indicate the presence of a pathological process, but they say little about the nature of the problem [63]. The definition of the initial pathological state (clinical problem) must therefore be somewhat isomorphic and congruent with the definition of the type of intervention applied (treatment) and with the definition of what is expected to change at the end of treatment with respect to the initial problem (outcome), investigating multiple levels simultaneously, as highlighted by Hoagwood, Jensen, Pretti and Burns [64], in order to have reliable outcome indicators available:

- Level I: *Symptomatic*. In most published research, symptom reduction remains the preferred criterion for defining a good outcome of therapy, despite its complexity. However, an evaluation of treatment that focuses exclusively on its influence on the most important symptoms may lead to an overestimation of the treatment's actual effect [65,66].
- Level II: *Adaptation*. Measuring the quality of the patient's relational life involves a wide range of events and situations, which makes it necessary to use multiple indicators in this area as well.
- Level III*: Functioning*. Mental functioning depends on both symptoms and adaptation to the context. It is therefore important to identify and specify the processes and mechanisms through which treatments achieve their results, emphasising the need to better define and outline the psychotherapeutic path in relation to "therapeutic" action.
- Level IV: *Contextual*. The set of contextual situations (e.g., family, community) that have a direct influence, positive or negative, on the subject's life.
- Level V: Satisfaction. The degree of satisfaction perceived by the patient (and possibly by family members).

As can be inferred from the above, psychotherapeutic treatment is so complex that its evolution is unpredictable: even minimal variations in the initial conditions produce effects which can be very significant and that are not deterministically connected to the conditions themselves. Therefore, in order to obtain an accurate representation of the process of change, it is necessary to have a measurement tool that, throughout the duration of the therapy, is able to detect useful indicators that are significant for improving the therapist-patient relationship, which is often the most important and decisive factor for effective psychotherapy [67-69].

For this reason, the Psychotherapy Evaluation Questionnaire (PEQ)[7] was designed and developed, which not only evaluates outcomes but also therapist-patient interaction based on three parameters: the relationship, motivation and adherence to therapy, sharing the opinion that psychotherapists, despite having different theoretical models of reference, must in any case share a common language and methodology in the evaluation of psychotherapy [70].

Method

Questionnaire development

The items were selected through four distinct phases:
Phase 1. Analysis of the scientific literature on psychotherapy evaluation.
Phase 2. Interpretation of the data collected and indications from the subjects to whom the questionnaire was administered in the pre-test phase.
Phase 3. Division of the items into four areas: a) Therapeutic relationship; b) Motivation for therapy; c) Adherence to therapy; d) Outcomes.
Phase 4. Experimental administration to a sample of subjects for psychometric evaluation.
The implementation of these phases made it possible to minimise the margin of ambiguity for the items as much as possible, while simultaneously facilitating a more accurate evaluation of psychotherapy.

A 4-point numerical Likert scale (from 0 to 3) was chosen to code the test responses, where "0" corresponds to "NEVER", "1" to "SOMETIMES", "2" to "OFTEN" and "3" to "ALWAYS".

The aim of the PEQ is to investigate the effectiveness of therapy during the therapy itself, by completing sections 1-3 of the questionnaire, which is administered to patients during therapy (sections 1-3 from the third session, with section 4 added from the eighth session). In this way, feedback on the treatment's progress can be obtained, and, if necessary, decisions can be made to modify the interventions according to the patient's needs. Providing therapists with feedback on the progress of therapy allows them to monitor changes in the patient in the following areas [70]:
- *The therapeutic relationship*. The therapeutic relationship, or therapeutic alliance, refers to the mutual agreement established between patient and therapist within a psychotherapeutic process regarding the goals of change, the tasks necessary to achieve those goals, and the establishment of a bond aimed at maintaining active collaboration between the parties, based on mutual trust and acceptance [71]. Several clinicians and researchers [72-74] have highlighted how this relationship represents a common factor across various psychotherapeutic approaches and is one of the most reliable predictors of outcome.
- *Motivation for therapy*. The term "motivation for therapy" refers to the patient's intention to change or review certain behaviours or beliefs to achieve significant positive results. When entering psychotherapy, each person may have a certain degree of willingness to change, which can be influenced by anxiety or fear of change, the degree of rigidity of their beliefs, and the effectiveness of psychotherapy or the psychotherapist [75,76].
- *Adherence to therapy*. A key element of the therapeutic act is the patient's "adherence" to the psychotherapist's suggestions and prescriptions, defined by the English term "compliance", which embodies the idea of a true therapeutic alliance and sharing. Patient compliance with psychotherapy is one of the most important issues in clinical practice, since the success of any intervention depends on the patient's effective adherence to therapy. Non-compliance with treatment, in fact, has as its direct consequences the inadequacy of treatment and the emergence of problems related to ineffective management of the pathology. The first step, then, in reducing non-adherence is to increase the patient's awareness of its importance through improved communication and greater knowledge of the underlying issues [77].
- Outcomes. The outcome in psychotherapy is defined as the result of the assessment (before, during and after the provision of a therapeutic service) of the behaviours, emotional states and adaptation of patients in relation to the reasons that led them to seek psychological therapy. In psychotherapeutic treatment, this is essential for increasing the level of knowledge on how to provide increasingly appropriate services in response to treatment needs, considering that meta-analyses clearly highlight how the Effect Size (statistical measure of the power of a treatment) of psychotherapy is superior to other medical treatments [78,79].

Therefore, a sudden reduction in the *relationship*, *motivation*, or *adherence* can be identified early on, allowing the psychotherapist to modify their intervention in relation to the patient's needs, overcoming their own *biases* and improving treatment outcomes. Based on these considerations, it is possible to identify the level of the areas investigated (Therapeutic Relationship, Motivation for Therapy, Adherence to therapy and Outcomes), transcribing the data collected with the Questionnaire in Table 2 and Table 3, from which it is then possible to identify the degree of Effectiveness of the therapy (The items reported in Table 2 are already grouped for scoring with respect to the individual areas, but in the patient's assessment, the items are distributed according to ascending numbering (1, 2, 3, ... 38, 39, 40) without identifying the areas they characterise [70].

Instead, if the entire questionnaire (Table 2) has been administered, to be carried out after the eighth session, the effectiveness of the therapy (ET) is calculated on the right-hand side of Table 3, the effectiveness of the therapy (EC) is calculated, reporting the sum of the "SO" in the "ΣSO" box, and the formula EC = (SSO/120) x 100 is applied, then transcribing the result in the box (EC), the meaning of which is expressed with 4 "judgements": "EXCELLENT" if the score is equal to or greater than 80%, "GOOD" if it is between 50% and 79%, "SUFFICIENT" if it is between 25% and 49%, and "POOR" if it is less than 24% [70].

Participants

The sample considered for this preliminary study consists of 427

7 In the preliminary study, this same tool was called the Questionnaire for the Evaluation of Psychotherapy (Q-EPT), but it was decided to change it to something simpler and easier to remember [70].

1. Therapeutic Relationship					
20. I have clear and comprehensible information about the therapy and how it works (costs, duration, etc.).	0	1	2	3	
38. I have someone who listens to me and speaks to me in a calm and balanced tone of voice	0	1	2	3	
13. I express my thoughts freely, without being subjected to any conditioning	0	1	2	3	
28. I have established a cordial relationship, but it cannot be described as friendly	0	1	2	3	
36. The therapeutic approach and areas of expertise were clearly explained to me	0	1	2	3	
34. I share the various stages of the psychotherapy project	0	1	2	3	
07. I ask for explanations about the techniques indicated by the therapist	0	1	2	3	
30. I establish an empathic relationship with the therapist (listens to what I say with interest, etc.)	0	1	2	3	
16. I feel comfortable with the therapist	0	1	2	3	
29. I feel helped to understand my behaviour better, without feeling judged	0	1	2	3	
2. Therapy Motivation					
02. I addressed with the therapist the difficulties that arose during therapy	0	1	2	3	
03. I contact the therapist, if needed, for advice between therapies	0	1	2	3	
05. I give notice in time in case of unexpected absences or delays	0	1	2	3	
31. I always respect the agreed time and manner of payment	0	1	2	3	
32. I agree with the therapist on the goals to be pursued with psychotherapy	0	1	2	3	
10. I carry out accurately the 'tasks' suggested by the therapist	0	1	2	3	
08. I feel free to choose what to address in therapy and when to do it	0	1	2	3	
37. I have enough space to express myself and be heard	0	1	2	3	
25. I look for information everywhere (internet, books, magazines, etc.) about my problem	0	1	2	3	
33. I compare myself, with respect to therapy, with my general practitioner, relatives, friends, etc.	0	1	2	3	
3. Therapy Adherence					
35. I feel I can trust the therapist who is on my side	0	1	2	3	
18. I am satisfied with my psychotherapy course	0	1	2	3	
04. I have a greater appreciation of my needs	0	1	2	3	
26. I am aware of some aspects of myself that I did not grasp before	0	1	2	3	
15. I feel I am listened to with interest and understood by the therapist	0	1	2	3	
24. I feel actively and collaboratively involved in therapy	0	1	2	3	
12. I reach my own conclusions through reflection	0	1	2	3	
22. I put the techniques I have been advised into practice immediately	0	1	2	3	
40. I often experience very strong emotions during therapy	0	1	2	3	
11. I feel helped to discover and develop my abilities to become autonomous and responsible	0	1	2	3	
4. Outcomes (not to be considered if the PsT started less than 8 sessions ago)					
01. I implement, in daily life, new behaviours that I have identified during therapy	0	1	2	3	
06. The feedback I receive from relatives and friends are indicators of a regained psychological wellbeing	0	1	2	3	
21. I make choices autonomously, evaluating all options adequately	0	1	2	3	
19. I can better control repetitive and/or impulsive behaviour that was previously out of control	0	1	2	3	
17. I can express my wishes, opinions and emotions to others	0	1	2	3	
09. I can propose myself and can decline others' offers	0	1	2	3	
14. I feel able to cope with life's challenges and difficulties without the need to resort to others	0	1	2	3	
27. I am more compassionate towards others, even if they have caused me sorrow	0	1	2	3	
39. I feel more comfortable in various life contexts and am more confident about the future	0	1	2	3	
23. If I felt the need, I would return to psychotherapy	0	1	2	3	

Table 2: Enter the scores obtained from the questionnaire in the table, divided into the four areas considered and enter the sum of the scores in the square to the right of each area.

PEQ	SO	MOS	EC
1. Therapeutic Relationship (7,13,16,20,28,29,30,34,36,38)		30	
2. Therapy Motivation (2,3,5,8,10,25,31,32,33,37)			
3. Therapy Adherence (4,11,12,15,18,22,24,26,35,40)			
4. Outcomes (1,6,9,14,17,19,21,23,27,39)			

ΣSO ☐ **EC** ☐

[EC = (ΣSO/120) x 100]

Table 3: The sums shown in the boxes with highlighted sides for each individual area (Therapeutic Relationship, Motivation for Therapy, Adherence to Therapy and Outcomes) are shown in the "SO" column (Score Obtained), then divided by 30 (Maximum Score Obtainable) and multiplied by 100; the result is transcribed in the "EC" column (Effectiveness Criterion for each individual area). The scoring of areas 1-3 only (Therapeutic Relationship, Motivation for Therapy and Adherence to Therapy, to be carried out after the third session) is adopted to give the therapist and patient the opportunity to familiarise themselves and share the emotional experience and is expressed with 4 "judgements": "EXCELLENT" if the score is equal to or greater than 80%, "GOOD" if it is between 50% and 79%, "SUFFICIENT" if it is between 25% and 49%, and "POOR" if it is less than 24%.

patients undergoing treatment at various psychotherapy practices in the Campania region, with different approaches (cognitive-behavioural, strategic, Gestalt and Systemic-Relational) aged between 24 and 79 (M=57), of whom 259 were female and 168 male, most of whom had been diagnosed with depression, obsessive-compulsive disorder (OCD), anxiety disorders, phobias, panic attacks (PA) and gender identity disorder. Patients were given a brief oral explanation of the questionnaire and asked to evaluate their experience in psychotherapy.

Pre-test

During the construction phase of the instrument, in order to examine the internal consistency of the items (item analysis) with respect to the various areas investigated, it was administered to 40 adult patients undergoing psychotherapy at various professional practices to verify the clarity and appropriateness of the items, listed in random order, and to obtain, in case of difficulty, indications for a linguistic and functional review of the items. At the end of this process, the Psychotherapy Evaluation Questionnaire (PEQ) was developed, consisting of 40 items divided into four areas, three of which analyse the progress of psychotherapy and one the outcomes of psychotherapy [70].

Results

Test-retest reliability and internal consistency

For the test-retest analysis, the questionnaire was administered to the entire sample. The data were analysed using the Interclass Confidence Interval (ICI), yielding very encouraging results with a value of 0.82 ($p < 0.01$).

Internal consistency, assessed using Cronbach's alpha, showed values ranging from 0.89 to 0.92 and was statistically significant for both the entire sample and the individual areas. The results are shown in Table 4.

Table 4: Evaluation of the internal consistency of the questionnaire using Cronbach's alpha.

Areas	Cronbach's Alpha
All SS	0,90
Relationship	0.92
Motivation	0.89
Adherence	0.91
Outcomes	0,89

Discussion

The aim of our study was to examine the reliability and internal consistency of the questionnaire created by one of the authors (G.M.G.) to evaluate psychotherapeutic intervention from a more evidence-based perspective.

The questionnaire yielded a good reliability value in the assessment, as indicated by the Interclass Confidence Interval, with a score of 0.78. In fact, one week later, the patients did not substantially change their answers.

The most satisfactory results in relation to the psychometric evaluation of the questionnaire are those related to its internal consistency. These values are very high for all subjects who participated in the study, with a Cronbach's alpha of 0.90. A high value in this aspect indicates a high consistency of the questionnaire, which is fundamental for effectively measuring the phenomenon under examination [63].

The subjects were motivated to evaluate psychotherapy, using the Likert scale in its entirety. The PEQ is a quick tool to administer, as it took less than 30 minutes to complete, and easy to understand, as in no case did the subjects leave any questions unanswered. However, the study has several limitations:

- The sample size is too small to provide an exhaustive assessment of the outcomes of psychotherapy, although it may be useful for gathering information on what happens (or has happened) during treatment (with regard to variables such as the relationship with the therapist, the perceived effectiveness of the therapy, satisfaction with expectations, etc.) and considering the objectives that were identified when the clinical project was formulated: remission (total or partial of symptoms), modification of certain aspects of personality functioning, partial or total resolution of any key issues, acquisition of better coping strategies, increased subjective well-being, increased social skills and prevention of "crisis" or exacerbation of symptoms.
- Importance of performing an Exploratory Factor Analysis to highlight which items saturate the factors and how many dimensions the instrument consists of.
- Identification of cut-offs ("Effective" if the score is equal to or greater than 80%, "Quite effective" if it is between 50% and 79%, "Not very effective" if it is between 25% and 49%, and "Not effective at all" if it is less than 24%) using ROC CURVES.

Conclusions

Over the last 70 years, many things have changed: clinicians are contributing more and more actively to research, reporting on the peculiarities of their work "in the field", stimulating researchers to develop methodologies and tools that are functional to clinical practice, and identifying which psychotherapies are effective. In reality, each model of psychotherapy (from cognitive-behavioural to systemic to integrated, etc.) has produced its own data over the years, and overcoming the "paradox of equivalence" has not determined "winners" and "losers" in the competition between schools, but rather a push to use the results of outcome-process studies (tailor-made) on those therapeutic factors that are "specific" to certain disorders, used differently in the various models. Thus, the terms of the debate on specific and non-specific factors no longer refer to the theoretical model, but to the psychopathological characteristics of patients, it being understood that theoretical consistency, the etiopathogenetic model and the methodological approach remain decisive. Compared to the 1980s, today, the data available on long-term follow-up studies on the effectiveness of different psychotherapies (in the treatment of most mental disorders and their stability over time) and the correlation between results and duration of psychotherapy (the longer the therapy, the greater the results and the higher the probability that they would consolidate) are much more reliable [80,81].

Today, a wealth of data is available on the effectiveness of psychotherapies and the stability of the changes achieved, as well as on the therapeutic relationship, which, in its various conceptual forms, is the most significant predictor of outcome. There is also growing consensus that psychotherapy is more effective when it is specifically oriented towards the psychopathological factors underlying the symptoms [67,68]. The therapist's years of experience and technical skills (including relational, personality-related, technical, empathic, etc.) are therefore brought into play in the construction of the therapeutic alliance [82-86]. Many studies have confirmed that the most effective psychotherapists are those who are best able to create deep alliances with a diverse range of patients, regardless of the relational skills and attachment patterns that the patient possessed at the beginning of therapy [69].

As far as the PEQ is concerned, it is desirable that the tool be studied with a larger sample and with a more appropriate and meaningful statistical analysis, and, at the same time, that it provide a clear and simple assessment of the psychotherapeutic process and can be used by the psychotherapist as a starting point for reflection to improve their performance [34].

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