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The long road ahead: challenges in defining and measuring change in RCTs on the effectiveness of long-term psychotherapy for personality disorders


Długa droga przed nami. Wyzwania w definiowaniu i pomiarze zmiany w badaniach RCT nad skutecznością długoterminowej psychoterapii zaburzeń osobowości

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Abstract

Introduction and objective: The growing emphasis on evidence-based practice in psychotherapy has increased the demand for high-quality empirical data supporting treatments for personality disorders. Long-term psychotherapy presents unique challenges in this area, especially in designing and implementing randomised controlled trials. At the conceptual level, these challenges arise from the multiplicity of mechanisms and the complex, time-extended trajectory of change. At the organisational level, such research requires elaborate procedures and substantial financial and human resources. A recent additional difficulty is selecting primary outcomes and appropriate assessment methods amid a field-wide shift from categorical to dimensional models of personality pathology. **Materials and methods:** This article outlines key considerations in designing and implementing randomised controlled trials evaluating long-term psychotherapy for personality disorders. **Results:** Four critical domains are discussed: (a) selecting a trial design that is appropriately aligned with the underlying research question, (b) the influence of the theoretical framework on conceptualisations of change and outcome selection, (c) the methodological and clinical implications of operationalising change, including the use of valid, reliable, and theoretically congruent assessment tools, and (d) the impact of procedural decisions on outcome validity – particularly concerning the temporal dynamics of change, early effects, and the divergent priorities of key stakeholders such as patients, clinicians, researchers, funders, and policymakers. **Conclusions:** The article emphasises the need for pragmatic adaptations that preserve scientific rigour while enhancing clinical and translational relevance. It aims to inform future efforts to develop theory-driven, methodologically sound trials of psychotherapy for personality disorders.

Keywords: personality disorders, long-term psychotherapy, randomised controlled trials, outcome indicators, dimensional models of personality disorders

Streszczenie

Wprowadzenie i cel: Rosnący nacisk na praktykę opartą na dowodach w psychoterapii zwiększył zapotrzebowanie na wysokiej jakości dane empiryczne potwierdzające skuteczność leczenia zaburzeń osobowości. Psychoterapia długoterminowa w tym obszarze wiąże się ze specyficznymi wyzwaniami, szczególnie w zakresie projektowania i realizacji randomizowanych badań kontrolowanych. Na poziomie koncepcyjnym trudności te wynikają z wielości mechanizmów zmiany oraz ze złożonej i rozciągniętej w czasie trajektorii procesu terapeutycznego. Z perspektywy organizacyjnej badania nad psychoterapią długoterminową wymagają złożonych procedur oraz znacznych zasobów finansowych i ludzkich. Dodatkowym wyzwaniem jest wybór głównych wskaźników zmiany oraz narzędzi ich pomiaru, również w kontekście przejścia od modeli kategoryalnych do wymiarowych w rozumieniu patologii osobowości. **Materiał i metoda:** Artykuł przedstawia główne zagadnienia związane z projektowaniem randomizowanych

badań kontrolowanych oceniających skuteczność psychoterapii długoterminowej w leczeniu zaburzeń osobowości. **Wyniki:** Analiza koncentruje się na czterech głównych obszarach: (a) doborze planu badania adekwatnego do pytania badawczego, (b) wpływie ram teoretycznych na konceptualizację zmiany i dobór jej wskaźników, (c) metodologicznych i klinicznych konsekwencjach operacjonalizacji tych wskaźników, w tym doborze trafnych, rzetelnych i spójnych z założeniami teoretycznymi narzędzi pomiarowych, oraz (d) wpływie decyzji proceduralnych na trafność pomiaru wyników – zwłaszcza w odniesieniu do trajektorii zmiany, wczesnych efektów leczenia oraz zróżnicowanych oczekiwań interesariuszy, takich jak pacjenci, terapeuci, badacze, instytucje finansujące i decydenci. **Wnioski:** W dyskusji podkreślono potrzebę pragmatycznych adaptacji w projektowaniu badań, które umożliwiają połączenie rygoru metodologicznego z kliniczną użytecznością. Celem artykułu jest wsparcie przyszłych, empirycznie ugruntowanych i teoretycznie spójnych badań nad skutecznością psychoterapii zaburzeń osobowości.

Słowa kluczowe: zaburzenia osobowości, psychoterapia długoterminowa, randomizowane badania kontrolne, wskaźniki zmiany, dymensionalne modele zaburzeń osobowości

INTRODUCTION

Considering growing pressure to implement evidence-based practices in psychology and psychotherapy (Widiger et al., 2024), there is an increasing demand from diverse stakeholders for empirical support demonstrating the effectiveness of interventions tailored to specific mental health conditions. One particularly complex area for researchers involves designing and conducting randomised controlled trials (RCTs) to evaluate the effectiveness of long-term psychotherapies for personality disorders (LTPPD). Research on personality disorders (PDs) presents particular challenges for trial design, as the pervasive and enduring nature of personality pathology requires long-term follow-up, multidimensional outcome assessment, and sensitivity to gradual and individualised change trajectories. Additional complexities arise from the heterogeneity of clinical presentations, high comorbidity rates, and variability in treatment response (Kramer et al., 2022). These factors contribute to the relative scarcity of high-quality, large-scale RCTs evaluating LTPPD and underscore the need for innovative and context-sensitive research strategies (Steinert et al., 2016).

The methodological rigour required by RCTs and the need to preserve the integrity of structured psychotherapeutic frameworks dedicated to treating PDs present investigators with numerous dilemmas and critical decision points (Montgomery et al., 2018). Difficulties in designing and executing such studies have also led to suggestions that the RCT model may not be adequate for evaluating the effectiveness of long-term psychotherapy for complex psychopathology, including PDs (Maat et al., 2007; Philips and Falkenström, 2021). While we acknowledge the issues

involved, we argue that RCTs can be a valid method for evaluating LTPPD, provided they are carefully prepared and procedurally adapted to the specific characteristics of the treatment. The key decisions concern the trial design and operationalisation and measurement of change – from selecting a theoretical framework and defining key outcome indicators, to choosing appropriate assessment tools and developing procedures that permit the observation and capture of meaningful change within the constraints of a controlled trial.

This article addresses four central areas pertinent to the planning and evaluation of LTPPD studies: (a) selecting a trial design that appropriately addresses the research question, (b) the influence of the theoretical framework on the conceptualisation of change and the identification of relevant outcome indicators, (c) the operationalisation of these indicators in a manner that balances methodological rigour with clinical relevance and allows for inclusion in meta-analyses and cross-study comparisons, and (d) the procedural aspects of RCT design that support the occurrence and measurement of change. Our goal is to guide the reader through the process of planning an RCT trial for LTPPD, regardless of the specific therapeutic modality employed.

This discussion is informed by a review of the existing literature on outcome measurement in psychotherapy and RCT methodology and our direct clinical and research experience. As authors, we have confronted many of the difficulties described in this paper while designing the TFPstudy.pl – an RCT evaluating the effectiveness of transference-focused psychotherapy (TFP) for borderline personality disorder (BPD). It is the first randomised trial of TFP planned in Poland, with three such studies completed to date globally (Clarkin et al., 2007; Doering et al., 2010; Giesen-Bloo

TFP is a manualised, evidence-based psychodynamic treatment developed specifically for individuals with personality pathology (Yeomans et al., 2015). The TFP approach is grounded in object relations theory and the associated model of personality organisation, which conceptualises personality functioning along a continuum from healthy to severely impaired. This model includes five core dimensions: identity integration, quality of object relations, predominant defence mechanisms, reality testing, and moral functioning (Caligor et al., 2018). The primary aim of treatment is structural change – namely, the improvement of intrapsychic functioning across these dimensions – ultimately leading to a higher level of personality organisation and better adaptation in domains such as relationships, work, and leisure. The main goal of the TFPstudy.pl is to evaluate the effectiveness of TFP in the treatment of BPD in comparison to treatment-as-usual (TAU), delivered by experienced clinicians within the Polish private psychotherapy system. A unique contribution of the TFPstudy.pl to the development of RCTs' methodology is its inclusion of outcomes related to dimensional model of personality disorder, along with changes in sexual functioning as a result of psychotherapy and the integration of qualitative methods into the analysis.

Box 1. A brief introduction to the TFPstudy.pl objectives

et al., 2006). We believe that our experience in planning the study, developing the RCT protocol, and navigating the ethical and procedural complexities inherent in LTPPD research enables us to offer viable – and we hope, methodologically robust – approaches to the challenges outlined in this article. Throughout the paper, we highlight key decisions by referencing specific solutions adopted in our project, which are presented in dedicated text boxes embedded within the article. Box 1 contains general information about the TFP and a brief summary of the TFP-study.pl project.

BETWEEN EFFICACY AND EFFECTIVENESS: POSITIONING LTPPD TRIALS ON THE CONTINUUM

The first critical decision in trial planning is selecting a design that appropriately addresses the research question, as RCTs serve different purposes depending on their design. Explanatory trials are conducted in idealised, highly controlled conditions to determine whether an intervention can work under optimal circumstances (efficacy).

In contrast, pragmatic trials are embedded in routine clinical settings and are designed to inform real-world decision-making – whether an intervention should be implemented in everyday practice (effectiveness) (Patsopoulos, 2011). These two approaches reflect different perspectives on clinical relevance: one emphasises internal validity and causal inference, while the other prioritises external validity and applicability.

Given these distinctions, one might reasonably ask whether any RCT on LTPPD truly qualifies as an explanatory (efficacy-oriented) trial – or whether, in practice, such studies inevitably resemble pragmatic (effectiveness-focused) designs, due to the many uncontrollable factors inherent in complex, long-term designs (e.g. changes in the patient's life circumstances, psychotherapist variability, patient heterogeneity, fluctuating motivation, treatment adherence, real-world setting constraints). Importantly, most clinical trials fall somewhere along a continuum between these two poles, rather than fitting neatly into either category. Therefore, identifying a trial's design is not a matter of binary classification but rather one of degree. This decision – finding the optimal balance between internal and external validity –

In the case of the TFPstudy.pl, we intentionally leaned toward pragmatism in several domains to enhance the applicability of our findings to the real-world settings in which TFP is typically delivered. Conversely, in domains where we adopted more explanatory features, we aimed to strengthen internal validity and the ability to draw causal inferences regarding treatment effects. Fig. 1 illustrates the level of nine PRECIS-2 domains in the TFPstudy.pl, along with brief justifications. The closer a point is to the centre, the more explanatory the trial design is.

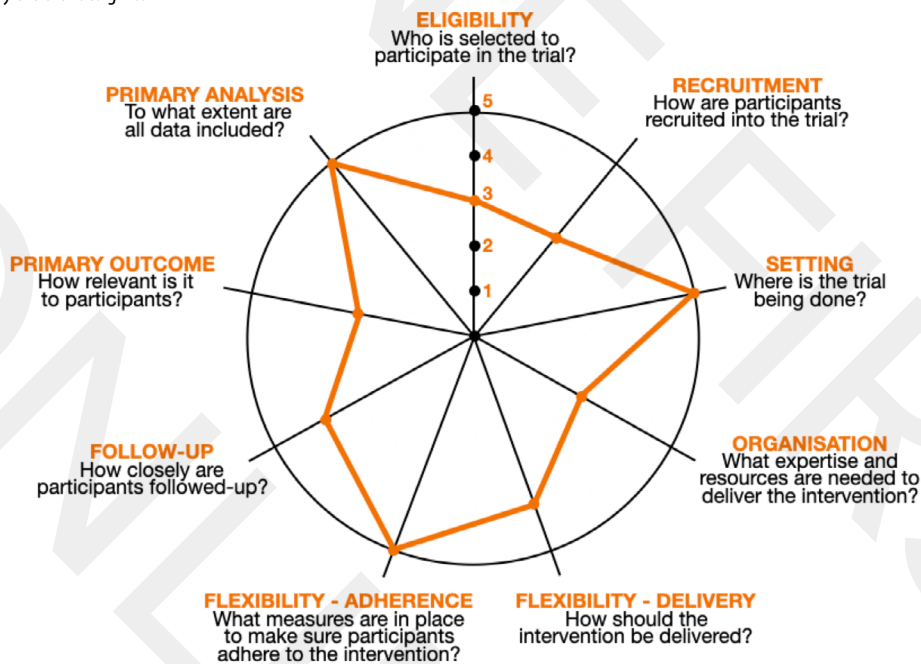


Fig. 1. PRECIS-2 wheel for the TFP-PL Study

Note. Because some PRECIS-2 ratings vary between trial arms, the figure presented here pertains exclusively to the TFP arm. Ratings were established through a team-based consensus process, drawing on examples and materials from the official PRECIS-2 toolkit (<https://www.precis-2.org>). **Eligibility:** Participants must meet full, more restrictive diagnostic criteria than typical care. **Recruitment:** Recruitment involves extra effort, including discounts and public announcements. **Setting:** Therapy is conducted in private offices, consistent with usual care in Poland. **Organisation:** Psychotherapists are highly experienced and receive more frequent supervision than usual. **Flexibility (delivery):** TFP delivery follows clinical norms, with adherence checks and supervision if needed. **Flexibility (adherence):** Patient adherence is monitored as in standard TFP, with no extra enforcement. **Follow-up:** Data collection occurs at 6 and 12 months; intensity is low and minimally intrusive. **Primary outcome:** The outcome is expert-rated and diagnostically grounded, but less directly relevant to the patients. **Primary analysis:** All available data will be analysed using an intention-to-treat approach (Loudon et al., 2015).

Box 2. Navigating between explanatory and pragmatic choices in TFPstudy.pl

is at the heart of designing clinical trials: we want findings that are both methodologically sound (i.e. validly demonstrate that the intervention caused the observed change) and clinically relevant (i.e. applicable to the kinds of patients we see in practice). We argue that every research team planning an RCT must undertake the critical task of navigating these choices. In what follows, we will illustrate this decision-making process using the example of the TFPstudy.pl, showing how our team balanced scientific rigour with real-world constraints in a specific research setting (see Box 2). One widely accepted tool for assessing this continuum is the PRECIS-2 (Pragmatic–Explanatory Continuum Indicator Summary) (Loudon et al., 2015), which helps researchers align trial design decisions with the study’s intended purpose. PRECIS-2 includes nine domains, each rated on a scale from 1 (*very explanatory*) to 5 (*very pragmatic*). Its simple wheel format facilitates structured discussion and consensus, promoting clarity in trial planning and transparency in interpreting results. The PRECIS-2 tool, while widely used, has known limitations – for example, in providing detailed criteria for assessing blinding or the nature of comparators. The forthcoming PRECIS-3 is expected to address these gaps and offer more comprehensive guidance for aligning trial design with purpose (Willis et al., 2024). We state that the inherent complexity of LTPPD trials makes purely explanatory designs virtually impossible to achieve. At the same time, an entirely pragmatic design would be impractical, as it could diverge too far from the rigour required to draw meaningful conclusions and offer limited utility for informing clinical decision-making. Instead, researchers must make strategic decisions about where their study will fall on the explanatory–pragmatic continuum and carefully consider these choices’ methodological and practical consequences. This positioning informs multiple downstream design decisions; in the following sections, we examine its implications with particular attention to eligibility, outcome selection and trial implementation logistics.

RETHINKING RCTs: CHALLENGES AND OPPORTUNITIES IN DIMENSIONAL MODELS OF PDs

In recent years, psychologists (researchers and practitioners) have faced the complexities of shifting from a categorical to a dimensional perspective in understanding PDs (Hopwood et al., 2018). This shift involves moving away from the long-entrenched belief that PDs can be diagnosed by recognising a specific set of symptoms characteristic of a given type. Instead, new dimensional models propose that PDs exist along a continuum between health and psychopathology across specific areas (American Psychiatric Association, 2013; World Health Organization, 2022). Over the years, numerous lines of evidence have accumulated in support of adopting dimensional models of PDs, which help to overcome many constraints of categorical models, such as the high rate of comorbidity between different types of PDs,

the frequent diagnosis of mixed PDs, and the tendency to assign diagnoses based on the presence of symptoms characteristic of multiple disorder types (Bach and Tracy, 2022; Widiger and Hines, 2022). PDs are conceptualised dimensionally across two major classification systems – ICD-11 and DSM-5. Both systems provide for the diagnosis of PDs in two areas: (a) the level of personality functioning (LPF; in DSM-5) or severity of personality dysfunction (in the ICD-11), which ranges from no personality difficulties to severe personality difficulties, and (b) maladaptive personality traits, which give the personality pathology its specific “flavour” (Sharp and Wall, 2021). In addition, the diagnosis according to the ICD-11 can be supplemented by the presence of a borderline pattern.

This shift in the conceptualisation of PDs has significant implications for assessment and research. Although the need for advancing clinical trials within dimensional frameworks is recognised (Zavlis et al., 2025), integration of such models into RCTs remains limited. To date, studies evaluating the effectiveness of psychotherapy have primarily relied on categorical models of PDs, with the majority of research focusing on individuals diagnosed with BPD (Kramer et al., 2022). A recent review of ClinicalTrials.gov (accessed June 2025) reveals only a few ongoing or planned studies based on the DSM-5 AMPD. Of these, only three explicitly target individuals meeting criteria for borderline or schizotypal PD under Section III, and only two utilise the Structured Clinical Interview for DSM-5 AMPD Module I for participant selection. In contrast, at least ten active or planned trials still employ traditional categorical BPD diagnoses, reflecting the continued predominance of traditional models in clinical research.

This hesitation may be due to the complexity of adapting dimensional models in clinical trials. Kramer et al. (2022) identified several areas where this will be particularly evident: (a) the selection of participants through inclusion and exclusion criteria, (b) the operationalisation and measurement of outcome variables, and (c) the statistical analysis of results. At the level of participant selection, dimensional models allow for moving beyond narrow diagnostic categories toward broader, more heterogeneous samples, addressing the issue of high comorbidity. However, this increased heterogeneity can complicate group-level interpretations and may obscure the detection of treatment effects specific to certain subpopulations. This problem, previously described by Kramer et al. (2022) in the context of high comorbidity among patients with PD diagnoses, may be even more pronounced when participants are selected based on dimensional criteria. For instance, including individuals who meet the diagnostic threshold for PDs as defined in ICD-11 may result in enrolling participants who, under ICD-10, would be classified into multiple PD types. One possible way to address this issue is to constrain variability within a given dimension, such as including only individuals with severe personality pathology, as defined in ICD-11, or selecting participants who exhibit specific dominant

In RCTs evaluating the effectiveness of psychotherapy, the comparison group often receives TAU. However, what constitutes TAU can vary considerably across studies, meaning that patients allocated to the control condition may receive very different types of care (see Watts et al., 2015). TAU may involve treatment by a primary care physician or general practitioner, psychotherapists practicing various modalities, or more eclectic forms of support. In some trials, the TAU condition is described insufficiently, making it difficult to determine what type of treatment was actually delivered.

From the perspective of evidence gathering, such heterogeneity has direct implications for the results of meta-analyses (e.g. Flückiger et al., 2014; Wampold et al., 2011). For researchers studying LTPPD, defining TAU poses an additional ethical challenge: the control condition must respond to the complex needs of patients with PDs, while relying on treatment mechanisms that are distinct from those of the experimental intervention. It would be unethical to involve patients in long-term treatment if there is no reasonable expectation that the care provided will offer genuine therapeutic benefit.

To address this challenge in the TFPstudy.pl, TAU will be delivered by certified psychotherapists from different modalities, all of whom have experience with treating PDs and receive regular supervision. At the same time, TAU therapists are required not to provide treatments that belong to the group of specialised, evidence-based approaches specifically designed for personality disorders (the “Big Four”) (Oud et al., 2018). We expect that this design will ensure that all patients receive appropriate and effective care, while allowing us to test superiority of the effectiveness of TFP as a specialised treatment for borderline personality pathology.

Box 3. TAU in RCTs: one concept, many approaches

In addressing the necessity of aligning theoretical constructs derived from object relations theory with the contemporary conceptualisation of PDs in diagnostic systems, the TFPstudy.pl incorporates the following solutions for the primary outcome measure:

1. Adoption of a hybrid model. The study includes participants with a categorical diagnosis of BPD, while outcome assessment is based on both improvements in dimensional measures of personality pathology (primary outcome) and reductions of BPD symptoms (one of secondary outcomes). This dual approach is intended to ensure comparability with existing and ongoing research grounded in the categorical diagnosis, while simultaneously aligning the study with the emerging dimensional paradigm and benefiting from its increased sensitivity to change.

2. Selection of constructs from the object relations theory. The study adopts theoretical constructs from the object relations model, which, through its concept of the level of personality organisation, also adopts a dimensional perspective to understanding personality disorders (Yeomans et al., 2015). It will allow us to capture specific and central changes to the TFP framework (such as identity diffusion or quality of object relations). Although these constructs are not equivalent to the dimensional models from ICD-11 or DSM-5 AMPD, given the conceptual overlap, our results will also be interpretable within ICD-11 and DSM-5 frameworks (Clarkin et al., 2020).

Box 4. Between object relations theory and dimensional models of PDs: TFPstudy.pl theoretical framework

pathological traits, as specified in the DSM-5 AMPD, which makes it possible to select a more homogeneous group (Kramer et al., 2022).

Outcome measurement challenges begin with choosing theoretical constructs that reflect changes in personality and align with the intervention’s theoretical background. Certainly, LTPPDs can aim to measure outcomes that are relatively well agreed upon and replicable in psychotherapy research on PDs, such as suicidality or self-harm behaviour, as these address crucial areas of impairment in this population (Stoffers-Winterling et al., 2022; Storebø et al., 2020). However, it is also possible to focus on more theory-specific constructs that help test targeted mechanisms, although this approach limits cross-study comparability. Given pluralism even in specialised therapies for PDs – transference-focused psychotherapy (TFP), dialectical behaviour therapy (DBT), mentalisation-based therapy (MBT), schema-focused therapy (SFT) (Oud et al., 2018) – consensus on key constructs and measures is unlikely. This is especially relevant in trials comparing interventions rooted in diverse therapeutic modalities, where modality-specific constructs and multiple measurement tools might be needed, increasing the methodological burden. An interesting example of combining non-specific and modality-specific measurements is provided by the study by Giesen-Bloo et al. (2006), which compared TFP and SFT. In this study, instruments such as DSM-IV-based BPD criteria and quality of life measures were used, alongside assessments derived from both TFP and SFT personality concepts – that is, schemas and the level of personality organisation. However, it is important to

note that demands associated with such complex approach – in terms of study duration, as well as the involvement of both diagnosticians and participants – can be substantial, particularly in the case when more resource-intensive methods like semi-structured interviews are used in the study. These concerns are less pronounced in studies comparing a single intervention to the TAU or a control condition such as waitlist groups, where the outcome framework can be limited to the theoretical model underpinning the treatment condition under investigation. However creating a TAU group presents specific challenges, which we briefly discuss in Box 3. Transdiagnostic frameworks such as the DSM-5 AMPD and ICD-11, along with their associated assessment tools – e.g. the Level of Personality Functioning Scale-Self Report (LPFS-SR) (Morey et al., 2017) and the SCID-5-AMPD – offer potential for enhancing comparability across studies, but also may compromise theoretical fidelity. The extent of this theoretical divergence likely varies across treatment modalities, depending on how closely the core constructs of a given therapy align with the dimensional frameworks proposed in the DSM-5 AMPD or ICD-11 (see Box 4 for an example).

Regarding outcome measures, it is also worth noting that dimensional models may offer a more nuanced view of change by capturing subtle shifts in personality that categorical approaches may overlook. This is particularly relevant in cases where outcome measures rely on arbitrary thresholds to classify individuals as “recovered” or “remitted”. Citing research by Zanarini et al. (2012) on BPD, Kramer et al. (2022) point out that a person meeting four

diagnostic criteria over time would be considered “remit-
ted”, while someone meeting five would not. Such dichotomisation results in a loss of clinically meaningful information, especially regarding differences in the severity of pathology. Kramer et al. (2022) also cite work by Markon et al. (2011), who showed that this kind of categorical classification can result in reducing reliability by about 15% and validity by 37%. These losses, in turn, diminish the statistical power of RCTs to detect treatment effects. Nevertheless, dimensional models are not without limitations, and threshold-based approaches continue to fulfil an important function. Group-level indicators, such as mean questionnaire scores, are not reliable for making inferences about changes at the level of individual participants. Consequently, change indices are frequently employed, thereby introducing a de facto threshold. This observation suggests that, despite the concerns associated with dichotomisation, threshold-based approaches may retain practical utility in the context of psychotherapy research.

About the implications of adopting a dimensional model for statistical analysis – as again noted by Kramer et al. (2022), referencing Mayer et al. (2020) – this shift holds significant potential for addressing the long-standing challenge of identifying what works for whom. Unlike categorical models, dimensional approaches allow for the application of statistical methods that incorporate latent variables, enabling researchers to model treatment effects while explicitly accounting for measurement error. This enhances the precision of outcome measurement and makes it possible to examine how treatment outcomes vary across individuals with different baseline characteristics. However, realising this potential depends on meeting specific methodological requirements. Researchers must ensure that relevant baseline covariates are measured before treatment and that sample sizes are sufficiently large to support the complexity of the models being used. The latter poses a particular challenge in the context of LTPPD, where factors like higher dropout rates make it more difficult to achieve the statistical power necessary for complex modelling.

Although a great effort has been made since the introduction of dimensional models to disseminate this thinking about PDs to practitioners and researchers (Bach et al., 2018), their use may still cause discontinuities with prior research, especially with prior RCTs, based on a categorical

model, complicating inclusion in meta-analyses and systematic reviews. Researchers adopting dimensional methods in RCTs on LTPPD should expect methodological isolation and reduced visibility (at least for a while), likely persisting given categorical dominance in current RCTs’ protocols. A pragmatic way to address these tensions may involve hybrid trial designs incorporating categorical and dimensional outcome measures. For instance, RCTs evaluating treatments for BPD could include traditional symptom-based assessments (e.g. remission of DSM-defined criteria) alongside dimensional measures of LPF. Such integrative approaches preserve continuity with existing research while advancing toward a more dimensionally-informed understanding of treatment effects, in line with contemporary models such as DSM-5 AMPD and ICD-11.

DEFINING CHANGE: SELECTING AND OPERATIONALISING OUTCOME INDICATORS IN LTPPD RESEARCH

A central challenge in evaluating the effectiveness of LTPPD lies in the precise definition and measurement of therapeutic change. This extends beyond the mere reduction of symptoms and requires capturing complex transformations in patient functioning and personality. The selection of appropriate indicators and measurement tools constitutes a critical methodological dilemma, influencing the research’s scientific validity and clinical relevance. In studies assessing the effectiveness of LTPPD, especially RCTs, a fundamental tension emerges between internal and external validity (e.g. Loudon et al., 2015; Patsopoulos, 2011). Prioritising internal validity calls for using assessment tools that are closely aligned with the theoretical model guiding the intervention, as these tools are more sensitive to capturing the specific outcomes or mechanisms of change postulated by that model. However, such measures may lack standardisation or comparability across studies, limiting generalizability and hindering their acceptance within broader clinical and academic communities. This tension profoundly shapes the credibility and applicability of findings. Box 5 describes how these issues were addressed in the design of the TFPstudy.pl.

A review of the literature (e.g. Storebø et al., 2021), combined with clinical experience, suggests that one

In the TFPstudy.pl, the primary outcome is defined as change in the level of personality organisation and personality functioning, while among the secondary outcomes we included the severity of BPD symptoms and the intensity of maladaptive personality traits. Accordingly, in designing the TFPstudy.pl, we faced two major decisions corresponding to the dilemmas outlined in Box 4: (a) whether to employ assessment methods based on categorical or dimensional models of PD, and (b) which instruments grounded in object relations theory would be most appropriate for evaluating personality pathology.

To address the first issue, we incorporated a categorical measure of BPD symptoms (SCID-5-PD interview) and dimensional assessments of personality pathology: the LPFS-SR questionnaire to evaluate Criterion A and the PID-5 to assess Criterion B. This hybrid approach enables us to remain aligned with existing research based on categorical diagnoses while also contributing to the growing body of work promoting dimensional models in studying LTPPD.

Regarding the second issue, we selected the Polish version of the Structured Interview of Personality Organization – Revised (STIPO-R-PL) (Soroko et al., 2025) to assess the level of personality organisation. This tool evaluates key dimensions such as identity diffusion, quality of object relations, and predominant defence mechanisms – all representing core therapeutic targets in TFP. By using STIPO-R-PL, we aim to capture meaningful changes in personality structure throughout treatment.

Box 5. Selection of primary and secondary outcome measures in the TFPstudy.pl

promising approach to addressing the challenges of measuring change in LTPPD research is using a multilevel assessment battery that captures therapeutic change in its full complexity. When designing an RCT, it is important to recognise that therapeutic change can be assessed across different levels of patient functioning and experience. The first level concerns changes in symptom severity, in line with the categorical understanding of mental disorders. This includes both symptoms specific to particular PD types – measured using dedicated instruments – and other symptoms such as anxiety or depression. These widely used, transtheoretical measures facilitate cross-study comparisons and support meta-analyses, contributing to the cumulative evidence base (Kappelmann et al., 2020). However, such tools may lack sensitivity to the changes critical to treating PDs, including changes in personality or interpersonal functioning (Zahediabghari et al., 2020). The second level of therapeutic change involves improvements in everyday functioning, including engagement in work and leisure activities, subjective well-being, and overall quality of life. To assess these areas, we advise including self-report instruments that capture the patient's perspective on life satisfaction and functioning across various domains. The third level pertains to changes in personality itself. This may be evaluated using instruments aligned with dimensional personality pathology models, including interviews and self-report questionnaires that assess LPF and maladaptive traits. The proposed division does not represent an exhaustive catalogue of all functioning areas that psychotherapy may affect. Instead, it is intended to stimulate reflection on the inherent complexity of outcome measurement in RCTs on LTPPD.

At the same time, it is important to note that the literature provides several comprehensive frameworks outlining tools for outcome measurement in psychotherapy research. One notable example is the outcome measurement set developed by the International Consortium for Health Outcomes Measurement (ICHOM) (Prevolnik Rupel et al., 2021), specifically designed for studies on PDs. This framework emphasises using a standardised set of instruments to enable meaningful comparisons across studies, while reducing the burden placed on participants. The ICHOM working group identified four key outcome domains to be assessed in research on PDs: mental health, behaviour, functioning, and recovery. The instruments they recommend correspond to various levels within the layered model of outcome measurement outlined above. Regardless of the selection strategy adopted, researchers consistently face the challenge of balancing a thorough, theory-driven approach with the practical constraints inherent in clinical trial design. This includes navigating trade-offs between the depth and breadth of assessment, managing the limitations of existing tools, and minimising patient burden. These decisions are shaped by methodological and logistical considerations and ethical imperatives concerning feasibility and participant well-being.

FROM THEORY TO PROTOCOL: DESIGNING RCTs TO CAPTURE CHANGE

The choice of theoretical constructs and tools for measuring change in the course of LTPPD entails further steps, such as designing a research procedure that enables the observation of change in the selected outcomes. In this section, we lean first into some of the problems in RCTs for LTPPD design including: (a) the expected timeframe for the emergence of change, (b) the duration of the study required to observe such change, (c) the stability of change during the study and follow-up phases, and (d) the possible coexistence of both positive and negative changes resulting from the applied interventions.

Capturing complexity: different levels of change in psychotherapy and research

The shift from a categorical to a dimensional model in understanding PDs allows for the conceptualisation of patient psychopathology in two areas: LPF and maladaptive personality traits (American Psychiatric Association, 2013; World Health Organization, 2022). Additionally, PDs often co-occur with other psychiatric conditions, which may also improve through personality disorder-focused psychotherapy. LPF, maladaptive traits, and symptoms of comorbid psychiatric disorders show different rates of change. Therefore, the minimum study duration required to observe the desired change may vary significantly.

The number of studies focused on observing changes in the LPF under the influence of psychotherapeutic interventions is steadily increasing, though most focus on short-term treatments. It is assumed that LPF is more amenable to change, as it may reflect problems noticeable to patients, unlike more egosyntonic maladaptive traits (Kiel et al., 2024). Several previous studies support this view, showing significant improvements in LPF among patients participating in various forms of short-term intensive psychotherapy (Kiel et al., 2024; Kraus et al., 2021; Kvarstein et al., 2023). These results also support the prevailing view that the LPF is crucial for patient retention in therapy and that patients with less severe personality pathology have greater capacity to benefit from offered treatment (Koelen et al., 2012; Vinnars et al., 2007). As a result of short-term intensive psychoanalytic psychotherapy changes were noted across all dimensions of level of personality organisation except for the primitive defences (Kraus et al., 2021). Because defence mechanisms are one of the primary intrapsychic mechanisms that sustain personality pathology, this may suggest that the noted changes reflected transient, compensatory adaptation rather than deep transformation of LPF due to the applied treatment intervention. It has been suggested that certain changes in LPF may result from stabilising a regressed personality structure caused by stress or a crisis situation the patient was experiencing at the time (Hopwood, 2025). Moreover, although the aforementioned studies

indicate the possibility of influencing LPF within a few months, the absence of follow-up measurements does not allow for conclusions about the durability of these intervention effects. For researchers focused on the long-term psychotherapeutic outcomes related to patients' LPF, it would be advisable to implement interventions lasting at least one year, with follow-up assessments scheduled at two years or more after treatment completion (Steinert et al., 2016).

In contrast to the LPF, maladaptive traits are generally considered more stable over time (Hopwood, 2025; Rodriguez-Seijas et al., 2020), although empirical evidence on the effectiveness of psychotherapy in changing maladaptive traits remains limited. A study by Kiel et al. (2024) found that, following short-term integrative, dynamic-relational psychotherapy, patients showed greater improvement in personality functioning than in maladaptive traits when compared to a control group. On the contrary, Rek et al. (2023) reported significant reductions in negative affectivity, detachment, and disinhibition during a seven-week course of cognitive-behavioural and schema therapy for depressive disorders. Additional insight comes from research on the malleability of normative personality traits. A meta-analysis by Roberts et al. (2017) demonstrated that Big Five traits – particularly emotional stability and extraversion – can change significantly through psychological interventions, typically over an average duration of 24 weeks. However, the current body of evidence does not yet allow for a definitive conclusion regarding the time needed to observe significant and lasting change in maladaptive traits.

The literature reports a significant proportion of patients with PDs having comorbid psychiatric diagnoses (Hayward and Moran, 2008). PDs often co-occur with depressive and anxiety symptoms (Doering et al., 2018; Jańczak and Soroko, 2025) or eating disorders (Heinzmann et al., 2025; Martinussen et al., 2017). At lower LPF, psychotic symptoms may also manifest (Gruber et al., 2023; Kernberg, 2019). PDs are also characterised by tendencies toward aggressive and self-aggressive outbursts (Gilbert et al., 2015; Reichl and Kaess, 2021), with suicidal and parasuicidal attempts common at lower LPF (Baus et al., 2014). Aggressive outbursts appear in co-occurring substance use disorders and harmful abuse, especially in severe personality pathology (Amini et al., 2023; Noaman et al., 2022). Problems in love and sexual functioning are also noted (Deschênes et al., 2024; see also Izdebska et al., 2026 in this issue). The LPF significantly influences differences in the remission of co-occurring disorder symptoms during short-term versus long-term psychotherapy (Knekt et al., 2017). Long-term psychotherapy shows more sustained effects through modifications at the level of the patient's self-image, consistent with the hypothesised core role of LPF (Lindfors et al., 2015). Furthermore, the severity of all five maladaptive traits correlates with various psychopathological symptoms (Gioletti and Bornstein, 2024). In sum, although current research is still limited, existing evidence suggests that reductions in the severity of personality pathology and maladaptive traits are associated

with a corresponding decrease in the overall symptom burden experienced by patients (Lowyck et al., 2013), necessitating longer study durations and additional follow-up measurements to determine the stability of observed changes.

Timing matters: aligning therapeutic change with the RCT timeline

As noted above, the pace and nature of changes in patient functioning may vary depending on the LPF and the presence and type of comorbid disorders. Different outcome domains may follow distinct temporal trajectories, likely reflecting differences in their underlying mechanisms of change (see e.g. Kazdin, 2007; Taubner et al., 2022). For example, behavioural and affective dysregulation may respond relatively quickly to changes in situational or relational contingencies, whereas improvements in personality functioning or identity integration typically unfold more gradually, which is consistent with object relations theory conceptualising structural change as a complex, step-by-step process in which self-other representations are progressively integrated over time (Owen et al., 2015; Yeomans et al., 2015). Moreover, research on nonlinear patterns of change challenges the implicit assumption that clinical improvement progresses smoothly and linearly (Hayes et al., 2007) highlighting that individual differences in the dynamics of change are also important. Change in psychotherapy, especially in psychodynamic or insight-oriented approaches, often follows a discontinuous trajectory and sometimes is abrupt (Hayes et al., 2007). Individual time-series studies show that symptom trajectories often involve periods of heightened within-person variability, transient exacerbations (e.g. symptom "spikes"), or sudden gains, marking transitions between relatively stable states rather than a simple monotonic trend (Hayes et al., 2007; Shalom and Aderka, 2020). Research so far indicates that therapies focused on PDs reduce self-harm and suicidal thoughts within the first year of treatment (Oud et al., 2018), which reflects a positive effect of the applied treatment intervention. At the same time, as therapy progresses, periodic mood declines may occur due to addressing difficult, previously inaccessible to conscious reflection, issues in therapy (Owen et al., 2015). From a therapeutic perspective, this signals progress. Also, regression periods are necessary to consolidate changes in personality. This dynamic is consistent with findings on the treatment course of other mental disorders such as depression (Hayes et al., 2007; O'Mahen et al., 2019) and anxiety (Hayes et al., 2007; Keller et al., 2014). From the patient's viewpoint, however, this may seem like a negative change; emotional distress may intensify at certain points in therapy as part of the change process. From a researchers' perspective, the dilemma lies in determining the nature of interventions' effect on specific outcomes. Clues may emerge through the observation of individual-level change dynamics. Severity of personality pathology may decrease even if seemingly negative symptom changes occur

TFP primarily targets changes in personality organisation, reflecting the gradual identity consolidation, based on the assumption that improvements in personality organisation will lead to reductions in comorbid problems. In patients with severe personality disorders, the TFP process typically unfolds over 2 to 5 years and consists of three main phases: (1) stabilisation of the patient's functioning, leading to a reduction in self-destructive and aggressive behaviours directed at the self and others; (2) exploration and working through of conflictual object relations, aimed at their integration and the consolidation of a more cohesive identity; (3) consolidation of therapeutic gains, which is accompanied by observable symptomatic and behavioural improvements corresponding to changes in the level of personality organisation (Caligor et al., 2018). Most existing studies have focused on symptom-level dynamics and have not yet mapped the temporal unfolding of specific mechanisms in TFP. Nonetheless, preliminary micro-longitudinal evidence from TFP (Meehan et al., 2023) suggests that change within TFP is granular and may unfold on distinct temporal scales. For instance, shifts in the patient's experience of the therapist often emerge earlier than similar shifts in everyday interpersonal contexts. Further evidence indicates that different domains – such as affective instability, identity diffusion, and interpersonal perceptions – indeed change at different paces during TFP (Cain et al., 2026). The TFPstudy.pl is designed to measure changes in primary and secondary outcomes after one year of therapy – thus capturing the initial and, to some extent, the middle phase of treatment – with follow-up assessments planned after two, three and five years. This design increases the feasibility of the study, although it may limit the ability to fully capture the long-term effects of treatment. During the early stages of therapy, fluctuations in symptoms and personality organisation are often considerable. Patients may experience periods of improvement as well as apparent deterioration – changes brought about by the start of psychotherapeutic work related to unconscious conflicts and the establishment of an alliance with psychotherapist. These fluctuations can complicate the assessment of personality functioning within the relatively short timeframe of 12 months of treatment.

Box 6. The pace of change in transference focused psychotherapy

simultaneously, indicating a shift from previously ego-syntonic problems to ego-dystonic ones that now cause the patient clear suffering. Nevertheless, empirical work directly comparing fluctuation patterns in symptom-level variables (e.g. reductions in impulsivity) versus more structural domains (e.g. identity integration) is still scarce. Future research – particularly long-term, multi-wave designs – will therefore be crucial for systematically testing whether the hypothesised temporal differentiation of mechanisms can be empirically verified. Follow-up studies are also essential for determining observed changes' long-term trajectories and durability.

In summary, when designing an RCT, one must anticipate the time needed for meaningful change, consider various changes that may occur in patient functioning meanwhile, and reconcile these expectations with the study's possible duration, often influenced by funding and other external factors beyond the researcher's control. The consideration of the temporal dynamics of change in selected outcomes for the TFPstudy.pl was discussed in Box 6.

MEETING EXPECTATIONS: NAVIGATING THE DEMANDS OF STAKEHOLDERS IN RCTs DESIGN AND IMPLEMENTATION

Throughout the article, we have alluded to the multiple perspectives from which psychotherapy and research can be experienced – those of patients, therapists, and researchers. We now address this more directly, as the meaning and outcome of psychotherapy often differ depending on the observer. For example, in their classic work, Strupp and Hadley (1997) proposed a tripartite model of mental health and therapy outcomes, suggesting that these can be evaluated from three distinct viewpoints: the patient, the psychotherapist, and society. Each of these parties holds different expectations regarding the course and outcome of recovery. In our view, due to the methodological demands and extended timelines of RCTs on LTPPD, this model can be expanded to include additional perspectives – e.g. those of researchers (in RCTs divided into three groups: Trial Management Group, Trial Steering Committee, and Data and Safety Management Committee), funding agencies, and policy makers –

who are directly or indirectly involved in the planning and implementation of the study (see Fig. 2). Below, we offer reflections on the roles of these various groups and how they influence one another – considerations that should be explicitly addressed in the design of an RCT on LTPPD.

Psychotherapists

In all RCTs on LTPPD, psychotherapists serve as treatment providers and typically expect working conditions consistent with their usual clinical practice and therapeutic modality. In healthcare systems where psychotherapy is not fully reimbursed (e.g. Poland), studies must often rely on private practice settings, requiring therapists to allocate time during their regular working hours to deliver study-based treatment. Another challenge involves negotiating session fees, often lower than standard rates, particularly in high-frequency treatments such as TFP, which requires twice-weekly sessions and can place considerable financial strain on patients. To support psychotherapist engagement under these conditions, researchers may offer indirect incentives (e.g. contributing to the advancement of the field, opportunities for professional development) and more tangible benefits, such as free, regular supervision provided by experienced clinicians (Doering et al., 2010).

Patients

People's motivations for entering psychotherapy and participating in psychotherapy research are multifaceted and extend beyond symptom reduction, even if that remains a central reason for seeking help (De Saeger, 2016). In designing RCTs trials, we must acknowledge that patients are both therapy clients and research participants. This dual role – requiring simultaneous engagement with the therapist and the research team – can be experienced as burdensome or even destabilising. Key aspects of the therapeutic process, such as hospitalisations, medication use, missed sessions, or alliance ruptures, are systematically monitored and reported to researchers, which may affect the dynamics of the therapeutic relationship. Moreover, participation

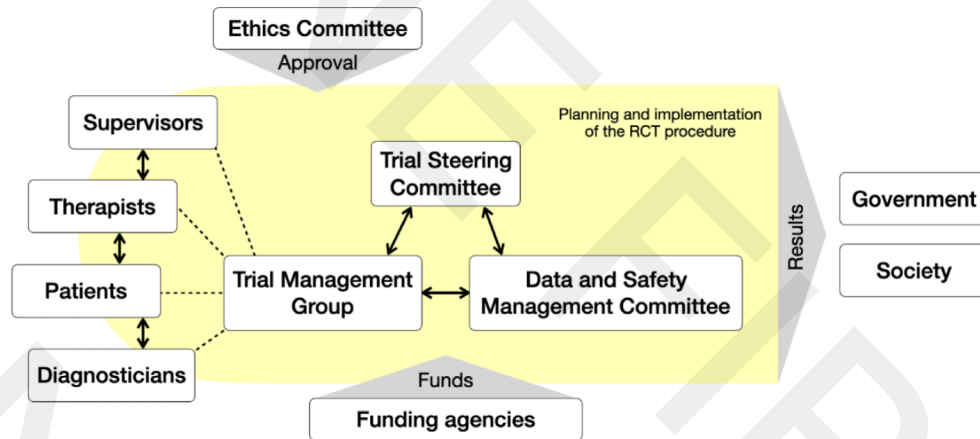


Fig. 2. Relationships among groups directly and indirectly involved in the planning and implementation of RCTs

entails accepting conditions that depart from routine clinical practice, including extensive diagnostic procedures (long interviews and questionnaires), repeated assessments, and random assignment to treatment conditions (see PRECIS-2 diagram above). Certain features of trial participation – such as free or reduced-cost of therapy, structured care, comprehensive assessment, and regular feedback – may enhance engagement. For example, implementing systems of routine outcome monitoring is highly recommended for improving the effectiveness of psychotherapy (Gonçalves et al., 2024; Hill and Norcross, 2023) and enhancing the experience of care (e.g. Boehnke and Rutherford, 2021). On the other hand, the added administrative and emotional demands can be particularly challenging for individuals with PDs. Although these challenges can often be addressed within the therapeutic process, they may also increase the risk of disengagement or dropout, which threatens both treatment continuity and the validity of the trial (Bell et al., 2013). These risks underscore the need for ongoing clinical supervision and proactive strategies to manage participant burden. More broadly, they highlight the importance of designing RCTs that are methodologically rigorous, psychologically feasible, and ethically responsible for participants with complex and enduring difficulties.

Funding agencies

Given the high cost of conducting RCTs – including partial or full coverage of therapy and/or supervision, personnel salaries, materials preparation, data management, and publication fees – substantial external funding is typically required. In some cases, funding agencies may be affiliated with the therapeutic modality under investigation. In such situations, researchers have an ethical obligation to safeguard the independence and integrity of the study. One way to safeguard this is to ensure that the Trial Steering Committee's decisions are free from the dominant influence of those responsible for funding – for instance, by appointing members who are

maximally neutral with respect to the anticipated study results (Medical Research Council, 2017). On the other hand, obtaining funding for psychotherapy research from public or independent grant agencies is often highly competitive and requires substantial time and effort. Regardless of the funding source, funding agencies expect successful project implementation within the awarded budget. However, RCTs on LTPPD are inherently complex, time-consuming, and prone to high dropout rates. They therefore may face difficulties in meeting these expectations without sufficient methodological flexibility and adequate resources.

Society and health policy

In the Polish context, ongoing public debate concerning the legal regulation of the psychotherapy profession and the role of psychotherapy within the public healthcare system adds further pressure for empirical validation of treatment interventions (Gazeta Prawna, 2025). Societal expectations and health policy increasingly aim to balance patient well-being with economic sustainability. As a result, researchers face growing demands to produce evidence-based findings that can inform both clinical decision-making and health system priorities. Conducting psychotherapy outcome research is therefore not only a scientific imperative, but also a prerequisite for ethical and responsible clinical practice, as it contributes to the identification of effective and efficient interventions (Kazdin, 2008).

In the literature, the cost-effectiveness of short- versus long-term psychotherapy remains a subject of ongoing debate – both from the perspective of individual patients and that of healthcare systems (Maljanen et al., 2016). Some evidence suggests that short-term interventions may be equally or even more effective than longer treatments in certain conditions (e.g. McMain et al., 2022; Poulsen et al., 2014). On the other hand, several authors argue that, despite their higher upfront costs, long-term psychotherapies may ultimately be more cost-effective due to the durability of their effects (e.g.

Lazar, 2014; Oud et al., 2018). It is argued that long-term interventions that target broad improvements in personality functioning (such as TFP) are based on the assumption that patients will become less dependent on mental health services and more capable of autonomous functioning in the long term – including maintaining employment, stable relationships, and overall life stability (Yeomans et al., 2015). From this whole-life perspective, the societal return on investment may prove substantial. However, empirical evidence on the effectiveness of long-term psychotherapy – particularly for PDs – remains limited and more research is needed to address this gap.

CONCLUSIONS

This article aimed to guide the reader through key areas in which researchers designing and conducting RCTs on LTPPD face decisions crucial for observing and measuring therapeutic change. Although not exhaustive, we have sought to present distinct methodological and conceptual challenges inherent in this type of research. Researchers must navigate the tensions between theoretical coherence, clinical relevance, and scientific soundness. While promising, the shift toward dimensional models of personality pathology raises complex questions about how to define and measure change within the time-limited and

structured format of RCTs. Choices regarding the conceptual framework, outcome indicators, and assessment tools must be carefully aligned to adequately capture the core processes of therapeutic transformation without compromising psychometric integrity or cross-study comparability.

However, the narrative presented in this article may risk giving the impression that such decisions follow a strictly sequential logic. Drawing on our own experience, we propose a more circular and systemic way of conceptualising RCTs' design, illustrated in Fig. 3. In this model, trial framing plays a central role: the initial decision about where the study falls on the explanatory–pragmatic spectrum serves as the foundation for all subsequent steps. This framing should also remain a reference point throughout the research process. Although decisions about defining change, selecting outcomes, operationalisation, and procedural design are typically made in a certain order, the process is inherently iterative. Researchers often revisit earlier decisions in light of new developments, adjusting them flexibly, though always within the boundaries of the initial framework. Thus, while choices may appear sequential, the designing and conducting of the RCTs should be understood as a dynamic and systemic process.

Such a flexible and creative approach demands continuous methodological reflection, close collaboration within the

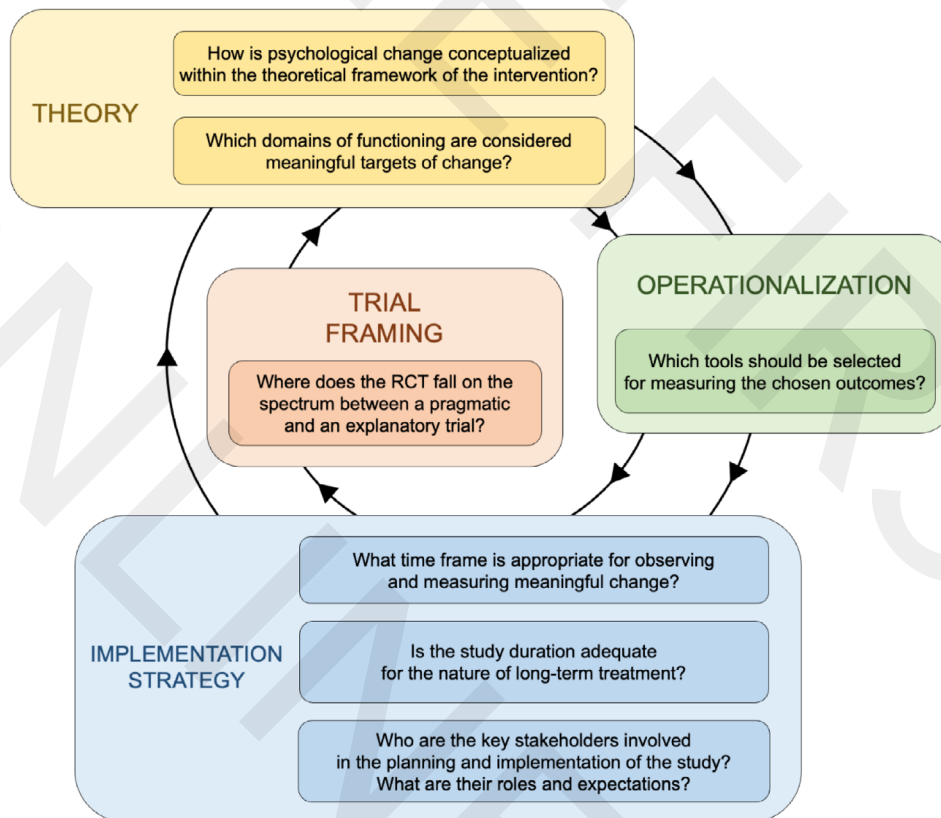


Fig. 3. An iterative approach to planning and implementation of an RCT on LTPPD

research team, sustained commitment, and an adequate time-frame. Ultimately, RCTs on LTPPD require an integrative mindset – one that bridges clinical depth with methodological precision – to ensure scientifically robust and clinically meaningful outcomes. This is a difficult but necessary endeavour, undertaken in the service of patients and psychotherapists alike, and in support of a future in which evidence-based practice becomes the standard and a shared responsibility.

Conflict of interest

The authors do not report any financial or personal connections with other persons or organisations which might negatively affect the content of this publication and/or claim authorship rights to this publication.

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Author contribution

Original concept of study: JB, AI, DZ, JF, MW, KWP, MS, MOJ. Collection, recording and/or compilation of data; analysis and interpretation of data; writing of manuscript: JB, AI, DZ, JF, MW, KWP, MOJ. Critical review of manuscript: JB, AI, MS, MOJ. Final approval of manuscript: JB, AI, DZ, JF, MW, KWP, MS, MOJ.

Monika Olga Jańczak contributed as senior author.

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