Process Based Therapy Applicability, Effectiveness and Compatibility (PBACE). A Within Therapist Randomized Controlled Trial Testing the Effectiveness of Process Based Therapy in Routine Patient Care and Assessing its Influence on Therapist Decision Making

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Abstract

Background: Process Based Therapy (PBT) is a novel approach for a more personalized psychotherapy by integrating patient's ecological momentary assessment (EMA) data into treatment planning and focusing on empirically measured maladaptive processes. Previous pilot studies have examined the efficacy and feasibility of PBT in different settings. However, the effectiveness of this approach as well as the influence of providing EMA data on therapist's decision-making as well as treatment planning is yet unexplored.

Objective: This study aims to evaluate the effectiveness of PBT in a naturalistic setting as well examine the influence of the provision of EMA data on therapists' decision-making.

Methods: Thiry therapists as well as 60 patients will be recruited. Therapists will each treat two patients which are randomly allocated to either an intervention group receiving PBT or an active control group receiving routine psychotherapy. Treatment outcomes will be measured pre and post treatment as well as a 6-month follow-up. Therapists' decision making will be measured before training in PBT as well as during the treatment process using think aloud protocols (TAP) as well as quantitative measurements for decision making styles and self efficacy in decision making.

Discussion: This study could add insights into the ongoing research about the efficacy and effectiveness of PBT as well as provide insights into therapists' treatment decisions. While PBT holds theoretical promise for a more personalized and effective treatment, empirical data is still needed to assess its theoretical merit, which this study could provide. Expanding on the thus far scarce literature on decision-making in the therapeutic process, valuable information about processes guiding therapists' treatment decisions could be gained.

Introduction

In mental health care, a wide range of psychological treatments are available, which have also been shown to be effective. A recent meta-analysis of uncontrolled studies of psychological interventions delivered in routine practice revealed that high pre-post effect sizes were associated with a reduction in depression and anxiety (Gaskell et al., 2023). However, it remains unclear whether positive effects assessed in studies can also be generalized to routine psychotherapy in mental health care, since clinical outcomes are rarely assessed and published. An exception is the Improving Access to Psychological Therapies program in England, which demonstrated that the implementation of stepped-care clinical guidelines may help bridge the gap between evidence-based research and practice (Clark et al., 2018).

However, treatment guidelines usually provide only rough recommendations for the use of evidence-based manuals related to diagnoses and leave open how the recommendations should be adapted to individual patients. Furthermore, empirical research indicates that in clinical practice, assessment of mental health problems is often unstructured, and interventions are mainly selected on the basis of personal experience or school-based treatment theories rather than empirical evidence (Gyani et al., 2014; Stewart et al., 2018).

Instead of developing more effective, new interventions, a promising approach to improve the outcomes of mental health care is personalization (Cohen et al., 2021). Personalization can be conceptualized as a process that involves a collaborative collection and processing of diagnostic information as well as shared decision-making in treatment selection. Personalization refers to treatment-related decisions that can be based on intuition and experience, theoretical models underlying treatment concepts, algorithms using scientific evidence for effective interventions, or precise statistical models used to predict the outcome of specific interventions on the basis of big data (Cohen et al., 2021). Preliminary results from randomized controlled trials indicate that the effectiveness of treatments may be increased by personalized treatments (Nye et al., 2023).

A key to personalizing treatment is to refine the adaptation of interventions to the individual problem and from research on active ingredients (Cohen et al., 2023). One possible way to select interventions more efficiently is by matching the specific mechanisms underlying psychological treatment to the psychological processes maintaining the psychological dysregulation of the individual patient. Following this concept, Hofmann and Hayes (2019) introduced the process-based therapy approach, which is characterized by two principles:

1. Identifying the key process maintaining maladaptive patterns via ecological momentary assessment (EMA) and dynamic network analysis (Hofmann et al., 2016)
2. Interventions should be selected according to scientific evidence for the ability to change this key process (Hofmann et al., 2020).

The process-based approach conceives of psychological disorders as individual networks of psychological processes, as opposed to the latent disease model, which assigns symptoms to an underlying disease (Borsboom & Cramer, 2013). In contrast to syndrome-based treatment packages, interventions are selected on the basis of change processes that have been empirically supported as mediators of treatment effects (Hayes et al., 2022). Furthermore, in an extended evolutionary meta-model, Hayes et al. (2020) proposed that mental health problems can be conceptualized as an idiographic network of maladaptive psychological processes in a specific context rather than as symptoms of a static state of disease. Within this evolutionary framework, change processes in psychotherapy are guided by the principles of variation, selection, and retention, modifying the elements of the maladaptive individual psychological network and creating an adaptive, more flexible network. Additionally, the more personalized approach in PBT holds the promise of treatment decisions that are based on empirical evidence rather than solely clinical intuition (Hofmann, 2025).

In summary, personalization is a promising way to improve the effectiveness of psychotherapy. However, whereas personalized treatment is associated with increased efficacy in randomized controlled trials, implementation in clinical practice may encounter barriers to data-driven and evidence-based decision algorithms (Gaudiano et al., 2011). Process-based therapy is characterized by two essential principles: 1) key factors maintaining psychological problems are identified via EMA and dynamic network analysis, and 2) interventions are selected on the basis of active ingredients that fit the key factors of the individual problem (Hofmann & Hayes, 2019). Furthermore, the effect of PBT on therapist decision making and treatment decisions has not been evaluated yet. In this study, the question, whether the diagnostic process and treatment selection, as intended in process-based therapy, are feasible for implementation and is effective in clinical practice is examined. Furthermore, the effect of training in PBT as well as the provision of EMA-data and idiographic dynamic network models during treatment on therapist decision making is examined. Since the principles of PBT are not related or are even restricted to specific disorders, patients with a broad range of diagnoses will be included in the trial.

Objectives

The main objective of this study is to examine the effectiveness of PBT in a naturalistic mental health care setting delivered by practitioners. To compare effectiveness between PBT and routine Psychotherapy, patients and therapists' ratings of mental health outcomes such as symptom severity and quality of life in a longitudinal design are compared. Further, the effect of PBT on therapists decision-making processes is assessed by comparing therapists' ratings of their decision-making as well as think-aloud protocols of therapists during treatment planning. The specific research questions for this study are the following:

- Is PBT more effective than routine Psychotherapy (r-PT) in a naturalistic setting?
- How does training in and implementation of PBT affect therapist decision-making?
- Does integrating EMA-data into the therapeutic process lead to more evidence-based treatment decisions?

The hypothesis derived from the literature and the research questions are as follows:

1a. Patients who receive PBT achieve better mental health outcomes after treatment as well as in a six-month follow-up than patients who receive r-PT. This effect is moderated by therapeutic alliance.

1b. Patients who receive PBT show a higher treatment adherence, general self-efficacy or confidence in treatment decisions.

2a. Therapists will shift to a treatment decision style that focuses on empirical evidence rather than other sources of information after being trained in PBT and maintain this direction over the course of treatment.

Methods

Study Design

The current trial is a randomized controlled effectiveness trial with two parallel treatment conditions, PBT and r-PT, delivered in a natural setting of mental health care. To control systematic effects of patient variables, such as treatment adherence and motivation, allocation will be stratified by patients. Patients will be randomly assigned to either the PBT- or the r-PT condition within one therapist's practice, meaning that therapists are treating patients in both groups. Thus, the present trial is conceptualized as a RCT with within therapist randomization. Adherence to both conditions is ensured by controlling the use of EMA and a questionnaire

covering essential elements of PBT. All participants across the two intervention groups will receive 24 weekly sessions. A CONSORT diagram is provided in Figure 1.

Additionally, decision making processes within therapists before and after training in PBT as well as based on the treatment that they are giving will be compared. Figure 2 shows a flow chart for measurement points for therapists.

Figure 1

Consort Flow Chart for the Present Trial

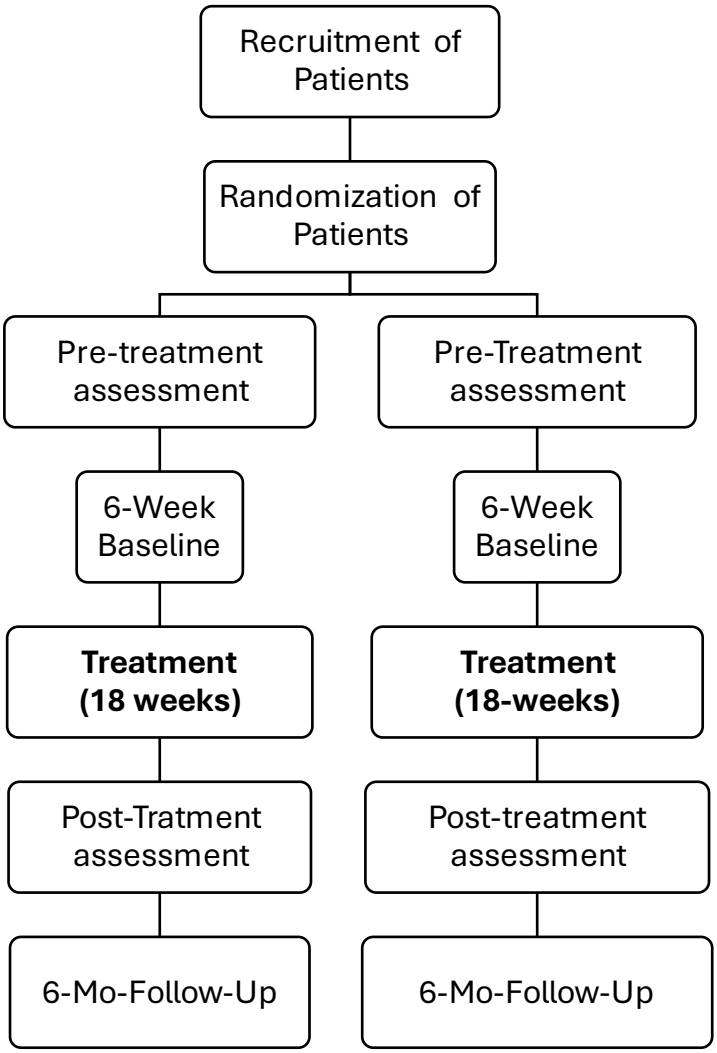
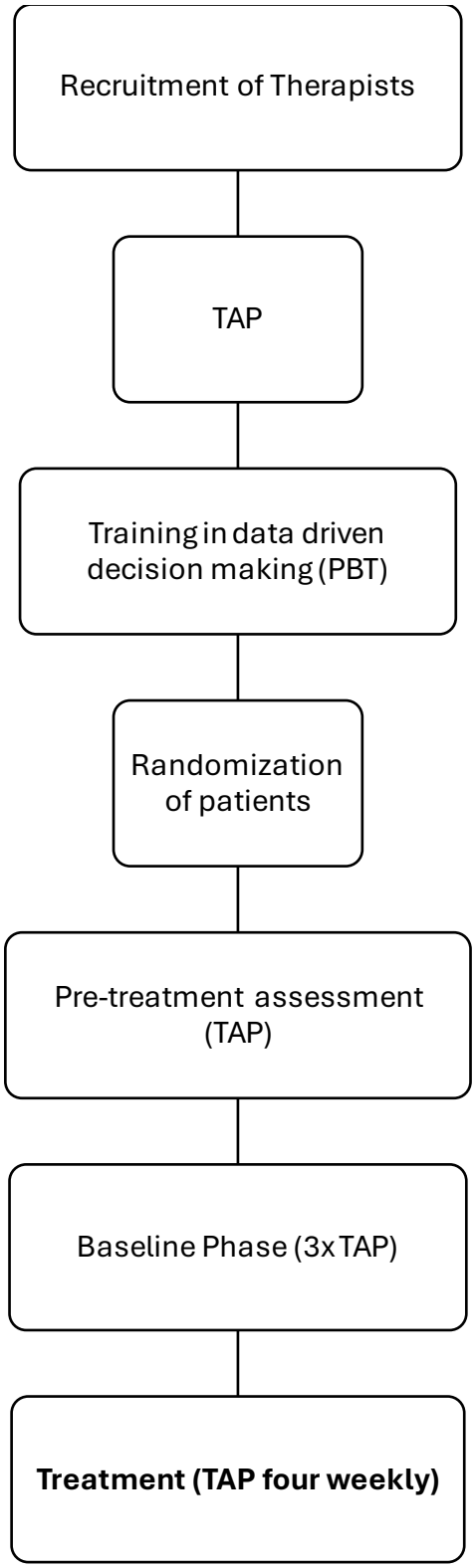


Figure 2

Flow Chart for Therapist Measurement Points



Assessment

Assessments of dependent variables are taken at four measurement points: before treatment, at intermediate, post treatment and at a six-month follow-up (Table 1). The intermediate measurement point is inserted at the session, where a dynamic network model is provided (~ 6 weeks after treatment start). For therapists, there are nine measurement points. The first measurement will be taken before training in PBT with the second to fifth being paired to the first session, the session where a diagnosis, the session where a hypothetical model is formed and the session where a dynamic network model is provided. For the control group, the measurement is matched to the session where the measurement took place in the intervention group. After these events, Measurements will occur every four weeks into the treatment phase (Table 2).

Table 1

Patient Measurement Plan

Time/Instrument	Pre-Assessment	Baseline Phase	Baseline-Assessment	Treatment Phase	Post Assessment	Follow-Up
DASS-21	x		x		x	x
PMH	x		x		x	x
CSQ-8	x		x		x	x
PAUEN			x (PBT)		x (PBT)	
EMA (PBT)		x (3x daily)		x (1x daily)		
TAPQ	x		x		x	x
GSE	x		x		x	x
DSE	x		x		x	x
WAI-SR-P	x		x		x	

Note. DASS-21: Depression Anxiety Stress Scale; PMH: Positive Mental Health Scale; CSQ-8, Client Satisfaction Questionnaire; PAUEN, Patient attitudes toward the utility of the EMA and network scale; TAPQ: Treatment Adherence Perception Questionnaire; GSE: General Self-Efficacy Scale; DSE: Decision Self-Efficacy Scale; Working Alliance Inventory-Short Revised (Patient Version)

Table 2

Therapist Measurement Plan

Time/Instrument	Pre-Training	Pre-Treatment	Baseline Phase	Baseline-Assessment	Treatment Phase (four weekly)
TAP	x	x	x (after diagnosis and hypothetical model)	x	x
TDMQ	x	x	x	x	x
TAUEN				x (PBT only)	x (PBT only)
TEI				x	x

Note. TAP: Think-Aloud-Protocol; TMDQ: Therapist Decision Making Questionnaire; SWD: Satisfaction with Decision Scale; T-SES: Therapist Self Efficacy Scale

Measures

Psychopathological Stress

To assess Psychopathological Stress, the Depression Anxiety Stress Scale (Lovibond & Lovibond, 2011) is used. The DASS-21 is a validated and reliable 21 item self-report instrument for the measurement of depressive and anxiety symptoms. Additionally, stress as a negative affective state is measured on an additional subscale.

Positive Mental Health and Quality of Life

Positive mental health and quality of Life will be measured using the positive mental health scale (PMH; Lukat et al., 2019) and the EuroQol-5D (EQ-5D; Brooks, 1996). The PMH is a validated nine item self-report scale for the measurement of the presence of positive mental health. Symptom severity measured by the DASS-21 subscales and positive mental health are considered the main outcomes of this study for the patient sample.

Feasibility Measures

Following a previous study on the feasibility of PBT in a naturalistic setting conducted by Hufschmidt et al. (n.d.), feasibility measures will be included in this study as secondary outcomes, to replicate findings from the previous study. Patient satisfaction at the end of treatment, measured with the Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982). Furthermore, the therapist attitudes toward the utility of the EMA and networks scale (TAUEN) and the patient attitudes toward the utility of the EMA and networks scale (PAUEN) are used, which are modified versions of the Therapist and Client Attitudes Measures by Frumkin et al. (2021). The Treatment Evaluation Inventory (TEI; Burgio & Sinnott, 1990) will be used to assess therapists' perceptions of treatment. It consists of 14 statements that are evaluated on a 7-point Likert scale, with response options spanning from −3 (strongly disagree) to +3 (strongly agree).

Self-Efficacy and Decision Making

Perceived general self-efficacy, meaning an optimistic self-belief that one can perform difficult or novel tasks or cope with adversity is measured by the General Self-Efficacy Scale (GSE; Schwarzer & Jerusalem, 2012). The GSE is a 10-item self-report questionnaire with a validated one factor structure. Additionally, to a general measurement of self-efficacy, domain specific decision making self-efficacy is measured using the Decision Self-Efficacy Scale (DSE; Bunn & O'Connor, 1996). The DSE is an 11-item self-report instrument measuring self-efficacy in the domain of treatment decisions.

Treatment Adherence

Treatment Adherence will be measured using the Treatment Adherence Perception Questionnaire (TAPQ; Sanford & Rivers, 2020). The TAPQ is a 16-item self-report instrument measuring the perceived adherence of patients to a specific treatment. It contains three subscales for the measurement of perceived benefit, perceived burden, and perceived behavior. Treatment adherence as well as self-efficacy and decisional self-efficacy are considered secondary outcomes for the patient sample in this study.

Therapeutic Alliance

Therapeutic Alliance is measured at patient level using the Working Alliance Inventory Short Revised Patient Version (WAI-SR-P; Wilmers & Munder, 2016). The WAI-SR-P measures therapeutic alliance from the patient's perspective using 12 items as a self-report.

Therapist Decision Making

Therapist Decision Making regarding treatment planning will be measured using think-aloud protocols (TAP). The think-aloud method is usually used to measure decision making in cognitive tasks such as problem solving (Someren et al., 1994), where participants are instructed to "think-aloud" meaning to verbalize their thoughts during a cognitive task. In this study, therapists will be instructed to verbalize their treatment planning at nine measurement points (see table 2). Given a maximum of ten minutes, with a minimum of five minutes, therapists will be able to verbalize any thoughts regarding treatment planning (for the exact instructions, see Appendix A).
Therapists' Decision-Making Styles and confidence in treatment decisions will be measured using the therapist decision making questionnaire (TDMQ; Fiehn et al., n.d.). The TDMQ is a self-report scale measuring therapists' decision-making style.

Participants

It is aimed to include $n_t = 30$ therapists treating $n_p = 60$ patients who meet the following inclusion criteria: (1) a primary ICD-11 diagnosis of a depressive or anxiety disorder, (2) age 18-65 years, (3) sufficient knowledge of the German language. Participating patients are not required to discontinue medication but rather to keep medication constant throughout the treatment period. Patients will be excluded in case of (1) increased suicidality, (2) substance abuse or dependency, (3) diagnosis of a cluster A or B (DSM-5) personality disorder, (4) pervasive developmental disorder, psychotic disorder, eating disorder, bipolar disorder, or severe physical illness. Inclusion and exclusion criteria are assessed by the psychotherapists who will determine the diagnosis according to ICD-11.

Recruitment and Randomization Procedure

Therapists will be recruited online via information about training in PBT. Therapists who agree to participate in the study will recruit patients from their individual practice. Patients are evaluated by therapists to be eligible for participation in the study based on the inclusion and exclusion criteria described previously. If patients are eligible for treatment, they will be provided with information about the project. Patients who consent to participate in the project will be included in the pretreatment assessment (see Table 1). Patients' self-ratings are collected electronically with the guidance of the trial management staff. Patients who cannot or will not participate in the study will be offered treatment as usual by the therapist.
If eligibility is confirmed and informed consent is given; the patient will be randomly assigned to

either the PBT or r-PT group. Patients will be randomized within a single therapist, meaning that therapists will assign two eligible patients which are then randomized to either group.

Treatments

Both treatments comprise 24 weekly sessions, including a 6-week baseline phase in PBT. In the baseline phase of PBT, a hypothetical network model of the problem is developed. EMA is then conducted based on the model's key components: situational context, cognition, emotion, bodily symptoms, behavior, cognitive processing, and motivational schema. In addition to the definition of maladaptive responses, the adaptive counterparts of the variables, representing the desired outcomes to be targeted in treatment, are also defined.

Participants of PBT are instructed to use the mobile app Status (Vacay ©), which prompts them to assess the seven dimensions from the hypothetical network model on a bipolar scale from -100 (maladaptive) to +100 (adaptive). Data are collected in the context of situations related to the problem. Therapists guide the adaptation of the items during weekly sessions and assist patients in recognizing situations and recording their judgments of the model components. EMA is completed when 100 measurements are collected.

Based on the EMA data, a dynamic network analysis is performed to assess autoregressive and cross-lagged effects of the variables (Epskamp et al., 2012). The interactive effects of the variables are estimated and visualized in a network where variables are represented as 'nodes', effects between them as directed arrows ('edges'), and autoregressive effects as 'self-loops'.

In the 6 initial sessions of r-PT corresponding to the baseline in PBT, no specific goals are prescribed. Usually, psychotherapists explore either current symptoms or major biographic events to gain insight into the psychological determinants of the problem.

After 6 sessions, the intermediate assessment is conducted, followed by 18 treatment sessions in both conditions. In PBT, treatment begins with a collaborative interpretation of the dynamic network model, which is based on EMA data collected during the baseline phase. Therapists identify the central node, significant edges, self-loops, and positive or negative feedback loops between the nodes (Stangier et al., 2024). Using the outcomes from the dynamic network model, interventions are selected based on empirical evidence for mechanisms of change that correspond to the individual patient's central node, as well as the feedback loops and self-loops, which are key in maintaining maladaptive patterns (Hofmann et al., 2020).

These interventions are framed within an evolutionary framework as the variation, selection, and retention of an adaptive mode of the central node in relation to the specific context of the problem

(Hayes, Hofmann, & Wilson, 2020). The change in this key variable is monitored through daily judgments based on EMA. Treatment also focuses on additional targets to establish adaptive modes of the dimensions as defined in the positive network model.

In r-PT, as opposed to PBT, a naturalistic setting is retained for treatment decisions. Treatment planning follows traditional theories about the factors maintaining the disorder and interventions to change it, e.g., avoidance and exposure in anxiety disorders or reduced reinforcement of activities and behavioral activation in depression (Wenzel, 2013). Interventions are selected based on common practices within schools of psychotherapy, such as Manuals for Depression within CBT. Individual data from the behavioral analysis are used to tailor the techniques to the individual problems of the patients. The treatment process is largely structured by the personal preferences of the therapist due to the experience, knowledge, or recommendations of the National Guidelines for Mental Health problems.

Statistical Analysis

For all statistical analyses, the statistical software R (R Core Team, 2024) will be used. Dynamic network analysis of EMA data at baseline and posttreatment will be computed using the R package "graphical VAR" (Epskamp et al., 2012).

Treatment effects for patients will be estimated using a Bayesian multilevel approach. The exact statistical models as well as the reasoning for the prior selection can be found in the supplementary material provided on the Open Science Framework (OSF). Two studies assessing PBT in their efficacy and feasibility will be used as empirical basis for the prior selection of treatment effects. Both trials are not yet finished. Once both trials are completed and their results have been published, the exact prior distributions for the assessed coefficients will be preregistered, which is expected to be at the end of 2026, well before any analyses on the data collected in this study will be performed.

For both analyses, therapeutic alliance will be included as a moderator for the treatment effect. Therapists recorded TAPs will be transcribed using the whisperX AI (Bain et al., 2023) and analyzed qualitatively using the content analyzation method according to Mayring (Mayring & Fenzl, 2019). Quantitative measures for therapist decision making style will be analyzed using a Bayesian multilevel regression model. The subscales, measuring specific therapist decision making styles will be included as outcomes in a multivariate hierarchical regression model with time and treatment group as within-subjects predictor and a random effect for therapist clusters. The exact statistical models can be found in the supplementary material.

Ethics and governance

This study is pending ethical approval by the Ethics Committee of the Department of Psychology of Goethe University Frankfurt. Protocol amendments will be communicated at https://clinicaltrials.gov and detailed in publications. Adverse events, particularly suicidal behavior/ideation, will be monitored. Withdrawal from the study will be considered in cases of increased suicidal ideation or acute suicidality.

Open Science

Analyses for this and all affiliated projects will be preregistered on OSF under https://osf.io/m68h2/. Supplementary material will be uploaded here as well and will be found under the respective projects.

Conclusion

This study is the first to investigate the effectiveness of PBT in a naturalistic setting. Further, the influence of PBT as well as EMA data on therapist decision making is examined. These findings might yield valuable implications for the improvement of mental health treatments, especially in terms of individualized diagnostics and treatment decisions.

First, the use of smartphone-based EMA implies that a hypothetical network model of the individual problem must be derived from exploration and then defined as dimensions that can be assessed in EMA. However, as some studies have noted, practitioners are skeptical of the application of digital assessment methods (Ellison, 2021; Frumkin et al., 2021; Lemey et al., 2019). The technical requirements also must be met (Degroote et al., 2020), which might limit its application.

Second, the outcome of dynamic network analyses of EMA data is dependent on the quality of the information covered in the smartphone-based assessments. Thus, the identification of relevant dimensions in exploration is an important challenge in the initial sessions before EMA is established at baseline. During the EMA phase, users must understand when and what is to be assessed, depending on whether time sampling or experience sampling is carried out. Furthermore, interpretation of empirical dynamic network models is an important initial step in organizing treatment. The identification of parameters such as central nodes, positive and negative feedback circles, and self-loops requires insight into the methodological background of

these parameters, which is not part of the current academic and clinical training. Furthermore, the communication of the results must be fitted to the patients' understanding, associated with obstacles concerning complexity, clarity, and utility for the treatment process (Hall et al., 2025).

Third, interventions are selected based on underlying mechanisms related to central nodes of the individual network rather than treatment packages or traditional treatment schemata. However, dynamic network models represent a challenge of the established practice, which is characterized by a strong link from syndromes to protocols or treatment packages (Hofmann & Hayes, 2019). The latent disease model claims that the problems of a person are caused by a latent dysfunction and is the target of the treatment. This model has determined scientific and clinical training and is deeply rooted in the clinical knowledge of many practitioners. The dynamic network approach, however, argues that psychopathological patterns represent an individual system of interacting elements of psychological symptoms (Borsboom, 2017). Therefore, the selection of personalized interventions based on information about the dynamic network model has not yet been established in clinical practice. Thus, the implementation of PBT requires "new" models, specific knowledge, and more complex decision processes that also consider the individual competencies of a therapist, which might limit its feasibility and effectiveness in practice.

From the patients' perspective, the implementation of EMA is associated with increased efforts. The collection of data in everyday life may not only be associated with digital distress but also require the interruption of automatic habits and a focus on psychological dimensions, as worked out in therapy. Thus, patients must refrain from avoiding negative emotions, face problems and judge their reactions. Thus, the capacity to accept distressing internal experiences is necessary to overcome experiential avoidance (Hayes et al., 1996). On the other hand, using bipolar ratings including positive dimensions may also motivate patients to engage in change processes even before therapeutic strategies are applied (Ciarrochi et al., 2022).

With respect to efficacy, the design and setting of our study are associated with significant limitations in internal validity. First, since therapists implement both treatment conditions, their therapeutic skills and attitudes will have profound effects on the delivery of PBT as well as on routine psychotherapy. Therapists' competence in applying specific decision-making strategies in PBT, their adherence to network-based interventions, and their allegiance with PBT will largely determine whether significant differences in effectiveness will be detectable. Although measures for adherence and allegiance can be applied to control for these factors, it is difficult to estimate

whether statistically significant differences can be achieved. Second, independent clinical judgments of the primary outcome are not included since organizing the timing with practitioners might create problems. Thus, there is a lack of objective information about treatment effects. Third, the inclusion criteria are broadly defined and allow for a heterogeneous composition of the sample with respect to diagnoses and severity. Although patients are randomized to both treatment conditions within therapists, the equivalence of subsamples with respect to clinical characteristics may be impaired.

In this study, the primary aim is to evaluate the effectiveness of the treatment in a naturalistic setting, with minimal interference in routine therapeutic procedures to ensure ecological validity and enhance generalizability to broader mental health care contexts. Further, this study could provide valuable insights into therapists' decision making processes with a core strength being the measurement through TAPs, thus providing a qualitative perspective in addition to quantitative measures. Although the current design is not fully powered for confirmatory testing of all mechanisms, it allows for a preliminary exploration of effectiveness and feasibility in real-world practice. If treatment effects are confirmed, subsequent randomized-controlled trials with larger sample sizes will be necessary to robustly evaluate the efficacy and mechanisms of the intervention.

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