Feasibility of process-based therapy in a naturalistic setting: Study protocol for a feasibility trial

NCT number: NCT06530888

Date of document: 05th of February 2026

Feasibility of process-based therapy in a naturalistic setting: Study protocol for a feasibility trial

Ulrich Stangier, University of Frankfurt, Germany
Bettina Hufschmidt, University of Frankfurt, Germany
Lucie Pahlen, University of Frankfurt, Germany
Viktoria Kohl, University of Frankfurt, Germany
Desiree Bonarius, University of Frankfurt, Germany
Arwin Nemani, University of Frankfurt, Germany
Mareike Ebert, University of Frankfurt, Germany
Stefan G. Hofmann, University of Marburg, Germany

Corresponding author:

Prof. Dr. Ulrich Stangier

Department of Clinical Psychology and Psychotherapy

Varrentrappstr. 40/42

D-60486 Frankfurt/Germany

Email: stangier@psych.uni-frankfurt.de

Abstract

Background

In the naturalistic setting of mental health care, the treatment decisions of psychotherapists are often based on theories or experiences related to treatment approaches. An alternative approach to treatment decisions is suggested by process-based therapy (PBT), which emphasizes empirical and rational criteria for the selection of interventions. It utilizes ecological momentary assessment (EMA) data, incorporates feedback from dynamic network analysis, and supports interventions to be chosen on the basis of individual network models and empirical evidence from research related to change processes. Currently, there are no data on the feasibility and acceptability of PBT in practice. The present study investigates, in a naturalistic setting, whether PBT can be implemented by psychotherapists in mental health care. Furthermore, we explored the acceptability and efficacy of PBT compared with psychotherapy delivered in routine practice (r-PT).

Methods

The study is an explanatory feasibility trial with two parallel treatment conditions. Forty patients are recruited in psychotherapy practices and allocated to one of two interventions, PBT or r-PT. To control for therapist effects, randomization is stratified by therapist.

Primary outcome is acceptance of the treatment by both therapists and patients, therapy expectations and dropout rates.

Secondary outcomes are patients' and therapists' attitudes toward the perceived benefits of the core PBT components and therapist-rated adherence to PBT rationale. Furthermore, as clinical outcomes, psychological symptoms of distress, depressive and anxious symptoms, patient-rated quality of life and psychological well-being will be compared between PBT and r-PT. Assessments of feasibility and clinical outcome variables will be conducted before, during, and after treatment.

Conclusions

The current study is the first to explore the implementation of PBTs in a naturalistic mental health care setting. If the feasibility of PBT is demonstrated, the results may provide new perspectives on the personalization of assessment and treatment on the basis of dynamic network analysis of EMA data and network-related treatment decision making.

Trial registration

Keywords

Process-based Therapy, dynamic network analysis, feasibility trial, ecological momentary assessment, clinical decision-making

Background

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 [1] revealed that high pre-post effect sizes were associated with a reduction in depression and anxiety. 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 [2].

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 [3,4]. Instead of developing more effective, new interventions, a promising approach to improve the outcomes of mental health care is personalization [5]. 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 [5]. Evidence from preliminary randomized controlled trials suggests that treatment effectiveness can be enhanced when interventions are tailored to the individual [6]. Achieving such personalization requires that therapeutic strategies be closely aligned with a person's specific difficulties and informed by research on mechanisms of change [7]. In this context, selecting interventions can be made more efficient by targeting the psychological processes that sustain an individual's dysregulation and matching them with treatments capable of modifying these processes. Building on this rationale, Hofmann and Hayes (2019) proposed the process-based therapy framework [8], which involves identifying the core processes that maintain maladaptive patterns using ecological momentary assessment (EMA) and dynamic network analysis [9], and then choosing interventions supported by empirical evidence for their capacity to alter these key processes [10].

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 [11]. 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 [12]. Furthermore, in an extended evolutionary meta-model, Hayes, Hofmann and Ciarrochi (2020) [13] 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.

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 [14]. 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 [8]. In our study, we examine the hypothesis that the diagnostic process and treatment selection, as intended in process-based therapy, are feasible for implementation in clinical practice. Furthermore, we sought to obtain preliminary indications of effectiveness of process-based therapy (PBT). Because the principles of PBT are not tied to, and may even transcend, specific diagnostic categories, the trial will include patients with a wide range of clinical diagnoses.

Objectives

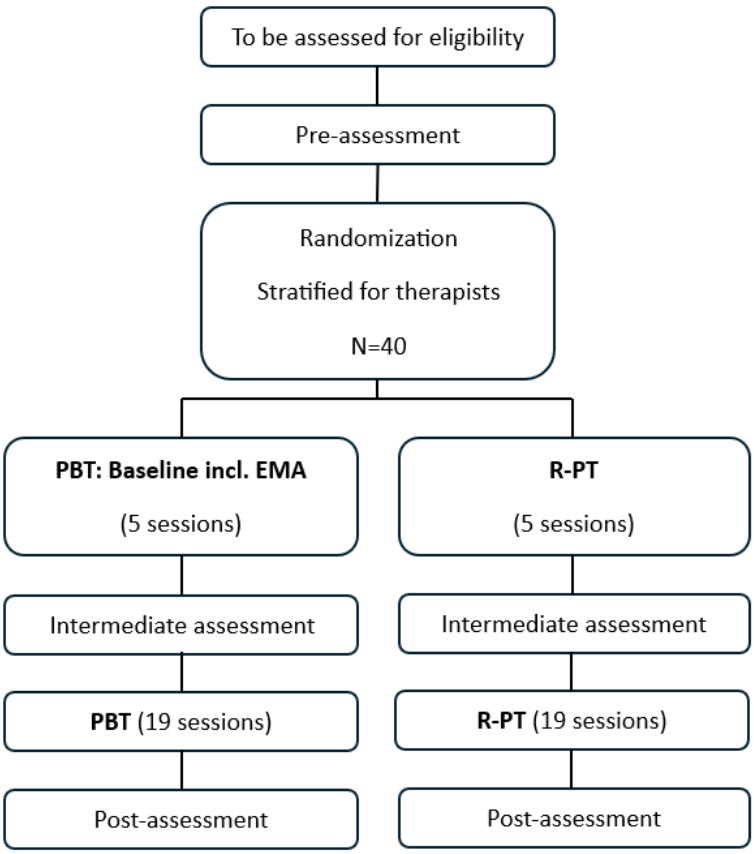
The main objective of this study is to explore the feasibility of PBT in a natural mental health care setting delivered by practitioners. Feasibility comprises therapists' and patients' evaluation of acceptance, utility, attrition of patients and adherence of therapists with the treatment. To determine the degree of feasibility, we compare patients' and therapists' ratings of feasibility related to PBT.
Overall treatment satisfaction will be considered a primary marker of how acceptable the intervention is to patients. This assessment will be complemented by patients' ratings of treatment credibility, their willingness to engage with ecological momentary assessment (EMA), and their level of compliance with EMA procedures. Therapists will report on the practical value of EMA and dynamic network models for their clinical work, as well as on the extent to which they followed process-based principles in their treatment decisions. Finally, trajectories of symptom burden and general mental health will be tracked to yield preliminary insights into the impact of PBT under routine clinical conditions.

Methods/design

Design

The current trial is an exploratory feasibility trial with two parallel treatment conditions, PBT and r-PT, delivered in a natural setting of mental health care. To control for systematic effects of therapist variables such as therapists' competences and preferences, allocation will be stratified by therapists. Pairs of patients recruited by a therapist within his practice will be randomly assigned to one of the two study conditions. Thus, the same therapist implements PBT as well as r-PT. Adherence to both conditions is ensured by controlling the use of EMA and a questionnaire covering essential ingredients of PBT. All participants across the two intervention groups will receive 24 weekly sessions. A CONSORT diagram is provided in Fig. 1.

Figure 1: Consort flow diagram



Notes: EMA: Ecological Momentary Assessment; PBT: Process-based Therapy; r-PT: Routine Psychotherapy

Assessments

Outcome measures for the dependent variables will be collected at three time points: prior to treatment, during treatment (intermediate assessment), and after treatment completion (see Table 1). The intermediate assessment takes place after five sessions in order to evaluate changes associated with the use of EMA.

The primary endpoints focus on treatment acceptability as an indicator of feasibility, based on both therapists' and patients' ratings obtained before and after the intervention. Additional feasibility indicators include therapists' appraisals of the intervention itself, their adherence to process-based clinical decision-making throughout treatment, and patients' level of compliance with EMA procedures.

Furthermore, postintervention changes in patients' self-reported emotional distress, psychological well-being, health-related quality of life, and overall mental health will be examined.

The process variables include psychological flexibility, reflective functioning, adaptive behavior and cognitive behavioral therapy skills at pre-, intermediate- and post-assessment. In addition, the therapeutic relationship will be assessed before and after treatment.

Table 1 Overview of measurements

Measurement Points		Inclusion	Pre-Treatment	Baseline Phase	Inter-mediate	Treatment Phase	Post-Treatment
Treatment Sessions				1-5		6-24	
Week Instrument		0	1	2-7	8	9-27	28
Therapist	ICD-10 Diagnosis	X					X
	CGI		X				X
	CGI-I						X
	HAQ-11		X				X
	FAMOS		X				
	Intervention Checklist						X
	PBDMQ					every 4 weeks (only PBT)	
	TAUEN						X (only PBT)
	CEQ		X				
	TEI						X (only PBT)
Patient	DASS-10		X		X		X
	EQ-5D		X				X
	PMH		X				X
	AAQ-II		X		X		X
	RFQ		X		X		X
	PBAT		X		X		X
	CBTSQ		X		X		X
	EMA (PBT)			Daily (only PBT)			X
	HAQ-11		X				X
	CEQ		X				
	PAUEN						X (only PBT)
	CSQ						X

Abbreviations:
HAQ-11, Helping Alliance Questionnaire;
FAMOS, Fragebogen zur Analyse Motivationaler Schemata, Kurzversion (Brief Assessment of Motivational schemas);
PBDMQ, Process-based decision-making questionnaire;
TAUEN, Therapist attitude toward the utility of the EMA and network scale;
CEQ, Credibility/Expectancy Questionnaire
TEI, Treatment Evaluation Inventory
DASS-10, Depression Anxiety Stress Scale 10 items;
EQ-5D, EuroQol 5 Dimensions;
PMH, Positive Mental Health Scale;
AAQ, Acceptance and Action Questionnaire
RFQ: Reflective Functioning Questionnaire;
PBAT, Process-based assessment tool;
CBTSQ, Cognitive behavioral therapy skills questionnaire
EMA: Ecological Momentary Assessment.
PAUEN, Patient attitudes toward the utility of the EMA and network scale;
CSQ-8, Client Satisfaction Questionnaire
CGI, Clinical Global Impression Rating Scales

Measures

Feasibility measures

Primary outcome. The main outcome will be patient satisfaction at the end of treatment, measured with the Client Satisfaction Questionnaire (CSQ-8) [18], which will be used as a central indicator of how well the intervention is accepted. In addition, study attrition will be evaluated, defined as the percentage of participants who withdraw before completing the final assessment. Attrition rates of less than 20% are typically regarded as acceptable [19].

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) [16]. The Treatment Evaluation Inventory (TEI) [17] 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).

Secondary outcomes. Perceived treatment credibility will be assessed prior to the start of therapy using the Credibility/Expectancy Questionnaire (CEQ) [15]. This instrument comprises six items, divided into two subscales that capture credibility and expectancy, respectively. Health-related quality of life will be measured both before and after treatment with the EuroQol-5D (EQ-5D) [20]. Positive psychological well-being will be assessed at the same time points using the nine-item Positive Mental Health Scale (PMH) [21]. Furthermore, levels of depression, anxiety, and stress will be evaluated with the short form of the Depression Anxiety Stress Scale (DASS-10) [22] at baseline, midtreatment, and posttreatment.

Psychological flexibility is measured by three self-reported items from the Acceptance and Action Questionnaire Version 2 (AAQ-2) [23]. Furthermore, reflective functioning will be assessed via the Reflective Functioning Questionnaire (RFQ-8) [24], a 54-item self-report inventory evaluating the capacity to comprehend the internal mental states of oneself and others across two dimensions: certainty and uncertainty about mental states. Using the process-based assessment tool (PBAT) [25], selection and

retention of adaptive behavior will be measured before treatment, at intermediate treatment and after treatment. The Cognitive–Behavioral–Therapy Skills Questionnaire (CBTSQ) [26], consisting of six self-reported items, was used to measure patients' use of cognitive behavioral therapy interventions in this study.

The FAMOS (Questionnaire for the Analysis of Motivational Schemata, short version), also known as the Brief Assessment of Motivational Schemata [29], captures motivational schemata by measuring how people structure their needs, goals, and motives and which motivational patterns they use in the process.

As a potential moderator of outcome, therapeutic alliance is assessed by patients and therapists via the 11-item Helping Alliance Questionnaire (HAQ-11) [30].

The diagnosis will be based on the International Classification of Disease-10 (ICD-10) and made by the therapists. At posttreatment, in addition to feasibility ratings for clinical utility and acceptance (see above), a checklist of interventions for therapists is implemented to verify adherence. The Process-based Decision-making Questionnaire (PBDMQ) [27] comprises 24 items designed to evaluate adherence to process-based therapy (PBT). The "Clinical Global Impression Scale" (CGI) [28] assesses the clinician's overall evaluation of the severity of a mental disorder and is utilized to monitor changes in symptom severity over time. It has 3 items that are answered by therapists.

EMA
The Status-PBT (Vacay ©, 2024) is a mobile application for the EMA during the baseline phase that uses personalized questions and captures six dimensions (thought, emotion, body sensation, behavior, cognitive processing, motivational schema) on bipolar continuous scales ranging from -100 to +100. The similarity of the context with typical problem situations as defined in the hypothetical network model is rated on a continuous scale ranging from 0 to +100.
A checklist of interventions for therapists is used after posttreatment assessment to check adherence based on literature reviews [31,32] and meta-analyses [33-36].

Settings

Therapists participating in the trial will be psychotherapists who are licensed for cognitive–behavioral therapy or psychodynamic psychotherapy for adult patients. Therapists will be recruited in Germany. All the therapists receive 20 hrs. training focusing on personalization of treatment by

1) deriving a hypothetical network model of the individual problem,
2) guiding patients through the collection of EMA data,
3) interpreting dynamic network models,
4) drawing network-related treatment decisions, and
5) applying interventions based on mechanisms related to the central knot of the network.

All therapists receive a manual [37] containing essential procedures in network-based assessment and treatment.

Participants

We aim to include 40 patients who meet the following inclusion criteria: (1) a primary DSM-5 diagnosis of a depressive or anxiety disorder, (2) age 18-65 years, (4)

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-10.

Recruitment and randomization procedure

Patients are evaluated by the 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 for the study is confirmed and informed consent for randomization is given, the patient will be randomized to one of two conditions (PBT or R-PT) provided by the same therapist. To allocate study participants to treatment conditions, a randomization list is created by the data management staff via the statistical software R. The group allocations are printed individually and placed in sealed envelopes. For each included participant, a member of the trial management staff draws an envelope and reads off the group allocation.

Treatments

Both treatments comprise 24 weekly sessions, including a 5-week baseline phase in PBT and a following tracking phase.
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 [38]. 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 5 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 5 sessions, the intermediate assessment is conducted, followed by 19 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 [39]. 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 [10].
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 [40]. 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 [41]. Interventions are selected based on common treatment manuals related to diagnoses, e.g., CBT for depression. 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.

Treatment fidelity

Adherence to PBT vs. r-PT treatment will be checked via a questionnaire assessing process-based and naturalistic decision-making styles [26]. The questionnaire, validated by PBT experts, contains 24 items. Therapists in both conditions will complete the questionnaire after every four sessions in each treatment. Additionally, after each treatment session, an intervention checklist covering frequently used interventions for depression and anxiety disorders will be completed.

Sample size justification

Power analysis with a formal sample size calculation is not considered to be adequate in feasibility studies [42]. To achieve a sufficient variance in patients’ and therapists’ responses, we intend to recruit, in line with recommendations reported in literature [43], a sample size of 40 patients. This sample size is considered to be sufficient to provide initial references for a feasibility trial.

Statistical analyses

Main outcome criteria for feasibility refer to descriptive statistics based on the criteria for utility and acceptance as defined in the section on feasibility measures. In addition, statistical analysis of measures will be based on completed assessments

but will not include intention-to-treat analysis. For the statistical analysis of the cross-sectional feasibility data at pre- and post-treatment, Mann-Whintey-U-Tests will be applied. Clinical outcome data will be analyzed using a repeated measures ANOVA with treatment condition as the between-subjects factor and time (pre-treatment and post-treatment) as the within-subjects factor. Secondary analyses of the data set generated in this study, such as exploratory moderator analyses and the analysis of secondary outcomes will be reserved. Any secondary analysis will be preregistered seperately from this study protocol. Dynamic network analysis of EMA data at baseline and posttreatment will be computed using the R package "graphical VAR" [38]. For all other statistical analyses, the computer program R will also be used.

Ethics and governance

The protocol has been approved by the Ethics Committee at the Department of Psychology (Registration number: NCT06530888). 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.
The first author, U.S., is the principal investigator (PI) and initiated the project together with the senior author, S.G.H. The study does not have a data monitoring committee.

Conclusions

This study is the first to investigate the implementation of PBT in a natural setting. Although the interventions used in PBT are not different from established psychotherapeutic methods, there are innovative elements that might be associated with barriers to implementation in practice.

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 [16, 44, 45]. The technical requirements also must be met [46], 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 [47].

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 [8]. 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 [48]. 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 [49]. 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 [50].

This trial will provide valuable insights into barriers to implementing PBT, which will help improve the conceptualization of decision processes in this new approach, as well as the training and supervision of therapists. However, with respect to effectiveness, the design and setting of our study are associated with significant limitations in internal validity. First, since therapists will 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 clinical outcomes 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 addition to these limitations, implementation in a natural setting of practicing psychotherapists with low interference with the therapeutic procedures ensures the generalizability of the outcome to the broader target of mental health care. Furthermore, in addition to providing information on the outcome, the practical experiences of psychotherapists will stimulate new ideas for improving the conceptualization and implementation of PBT. We have included quantitative criteria for determining the feasibility of the new treatment which focus on clinical utility and acceptance by therapists and patients. Feasibility will be further assessed by measures for patient's expectations and of therapists' adherence with the treatment principles. In addition, we also include ratings of quality of life, psychological symptoms and measures referring potential mediators of treatment effects. Although the design of this study does not allow for valid conclusions about the effectiveness of the treatment, these measures may provide additional information about the potential effects of the treatment. If the criteria for feasibility are met, randomized-controlled trials with adequate sample sizes are needed to test the efficacy of the treatment.

Declarations

Ethics approval and consent to participate

The protocol has been approved by the Ethics Committee at the Department of Psychology (Registration number: 2026-00B as a supplement to 2023-47). Protocol amendments will be communicated at https://clinicaltrials.gov and detailed in publications.

Consent for publication

Not applicable.

Availability of data and material

The study protocol is made publicly available through this publication. The main results are intended to be published in a high-impact peer reviewed journal within 6 months after the trial end date (approximately 2026/27). Individual participant data will be available for investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Data will be available beginning 6 months and ending 36 months following article publication.

Competing interests

All authors declare that they have no conflicts of interest.

Funding

This work is funded by the LOEWE Top Professorship for Stefan G. Hofmann, and supported by the DYNAMIC center, which is funded by the LOEWE program of the Hessian Ministry of Science and Arts (Grant Number: LOEWE1/16/519/03/09.001(0009)/98).

Authors' contributions

US and SH conceived the trial, drafted the study protocol and treatment manual, trained therapists and diagnosticians, and supervised implementation and coordination of the study. BH contributed to the trial design and protocol development and obtained ethical approval. ME and AN developed the EMA assessment and dynamic network analyses. LP, VK and DB conduct recruitment and data collection. US drafted the article and all authors read, edited, and approved the final manuscript.

Acknowledgements

We would like to thank Steve Hayes from the University of Nevada for supporting the development of our treatment manual and for contributing valuable ideas to the implementation of EMA into practice.

References

1. Gaskell C, Simmonds-Buckley M, Kellett S, Stockton C, Somerville E, Rogerson E, Delgadillo J. The Effectiveness of Psychological Interventions Delivered in Routine Practice: Systematic Review and Meta-analysis. Adm Policy Ment Health. 2023;50(1):43-57. doi:10.1007/s10488-022-01225-y.
2. Clark DM, Canvin L, Green J, Layard R, Pilling S, Janecka M. Transparency about the outcomes of mental health services (IAPT approach): an analysis of public data. Lancet. tria2018;17;391(10121):679-686. doi:10.1016/S0140-6736(17)32133-5.

3. Gyani A, Shafran R, Myles P, Rose S. The gap between science and practice: How therapists make their clinical decisions. Behav Ther. 2014;45(2):199-211. doi:10.1016/j.beth.2013.10.004.
4. Stewart RE, Chambless DL, Stirman SW. Decision making and the use of evidence-based practice: Is the three-legged stool balanced? Pract Innov (Wash D C). 2018;3(1):56-67. doi:10.1037/pri0000063.
5. Cohen ZD, Delgadillo J, DeRubeis RJ. Personalized treatment approaches. In: Barkham M, Lutz W, Castonguay LG, editors. Bergin and Garfield's handbook of psychotherapy and behavior change. 50th anniversary edition. 7th ed. John Wiley & Sons, Inc.; 2021. p. 673-703.
6. Nye A, Delgadillo J, Barkham M. Efficacy of personalized psychological interventions: A systematic review and meta-analysis. J Consult Clin Psychol. 2023;91(7):389-397. doi:10.1037/ccp0000820.
7. Cohen ZD, Barnes-Horowitz NM, Forbes CN, Craske MG. Measuring the active elements of cognitive-behavioral therapies. Behav Res Ther. 2023;167:104364. doi:10.1016/j.brat.2023.104364.
8. Hofmann SG, Hayes SC. The Future of Intervention Science: Process-Based Therapy. Clin Psychol Sci. 2019;7(1):37-50.
9. Hofmann SG, Curtiss J, McNally RJ. A Complex Network Perspective on Clinical Science. Perspect Psychol Sci. 2016;11(5):597-605.
10. Hofmann SG, Curtiss JE, Hayes SC. Beyond linear mediation: Toward a dynamic network approach to study treatment processes. Clin Psychol Rev. 2020;76:101824.
11. Borsboom D, Cramer AO. Network analysis: an integrative approach to the structure of psychopathology. Annu Rev Clin Psychol. 2013;9:91-121.
12. Hayes SC, Ciarrochi J, Hofmann SG, Chin F, Sahdra B. Evolving an idionomic approach to processes of change: Toward a unified personalized science of human improvement. Behav Res Ther. 2022;156:104155. doi:10.1016/j.brat.2022.104155.
13. Hayes SC, Hofmann SG, Ciarrochi J. A process-based approach to psychological diagnosis and treatment: The conceptual and treatment utility of an extended evolutionary meta model. Clin Psychol Rev. 2020;82:101908. doi:10.1016/j.cpr.2020.101908.
14. Gaudiano BA, Brown LA, Miller IW. Let your intuition be your guide? Individual differences in the evidence-based practice attitudes of psychotherapists. J Eval Clin Pract. 2011;17(4):628-634.
15. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry. 2000;31:73-86. doi:10.1016/S0005-7916(00)00012-4.
16. Frumkin MR, Piccirillo ML, Beck ED, Grossman JT, Rodebaugh TL. Feasibility and Utility of Idiographic Models in the Clinic: A pilot study. Psychother Res. 2021;31(4):520-534. doi:10.1080/10503307.2020.1805133.
17. Burgio LD, Sinnott J. Behavioral treatments and pharmacotherapy: Acceptability ratings by elderly individuals in residential settings. Gerontologist. 1990;30(6):811-816.
18. Attkisson CC, Zwick R. The client satisfaction questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982;5(3):233-237. doi:10.1016/0149-7189(82)90074-x.
19. Teresi, J. A., Yu, X., Stewart, A. L., & Hays, R. D. (2022). Guidelines for designing and evaluating feasibility pilot studies. Medical care, 60(1), 95-103.
20. Janssen MF, Pickard AS, Golicki D, et al. Measurement properties of the EQ-5D-5 L compared to the EQ-5D-3 L across eight patient groups: A multicountry study. Qual Life Res. 2013;22:1717-1727. doi:10.1007/s11136-012-0322-4.
21. Lukat J, Margraf J, Lutz R, van der Veld WM, Becker ES. Psychometric properties of the Positive Mental Health Scale (PMH-scale). BMC Psychol. 2016;4:8. doi:10.1186/s40359-016-0111-x.
22. Halford WK, Frost ADJ. Depression Anxiety Stress Scale-10: A Brief Measure for Routine Psychotherapy Outcome and Progress Assessment. Behaviour Change. 2021;1–14. doi:10.1017/bec.2021.12.

23. Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, et al. Preliminary Psychometric Properties of the Acceptance and Action Questionnaire–II: A Revised Measure of Psychological Inflexibility and Experiential Avoidance. Behav Ther. 2011;42:676–88.
24. Fonagy P, Luyten P, Moulton-Perkins A, Lee YW, Warren F, Howard S, et al. Development and validation of a self-report measure of mentalizing: The Reflective Functioning Questionnaire. PLoS One. 2016;11(7):1-28.
25. Ciarrochi J, Sahdra B, Hofmann SG, Hayes SC. Developing an item pool to assess processes of change in psychological interventions: The Process-Based Assessment Tool (PBAT). J Contextual Behav Sci. 2022;23:200-213.
26. Jacob KL, Christopher MS, Neuhaus EC. Development and Validation of the Cognitive–Behavioral Therapy Skills Questionnaire. Behav Modif. 2011;35:595–618.
27. Sendig L, Kohl V, Hufschmidt B, Görg N., Bonarius D, Nemani A, Ebert M, Stangier U, & Hofmann, S.G The process-based decision-making questionnaire (PBDMQ). in preparation
28. Guy W. Clinical Global Impressions Scale. APA PsycTests. 1976
29. Holtforth MG, Grawe K. Fragebogen zur Analyse Motivationaler Schemata (FAMOS). Z Klin Psychol Psychother. 2000;29(3):170–9. doi:10.1026/0084-5345.29.3.170.
30. Alexander LB, Luborsky L. The Penn Helping Alliance Scales. In: Greenberg LS, Pinsof WM, editors. The psychotherapeutic process: A research handbook. New York: Guilford Press; 1986. p. 325-366.
31. Hayes SC, Hofmann SG. Process-based CBT: The science and core clinical competencies of cognitive behavioral therapy. Oakland: New Harbinger; 2018.
32. Curtiss JE, Levine DS, Ander I, Baker AW. Cognitive-Behavioral Treatments for Anxiety and Stress-Related Disorders. Focus (Am Psychiatr Publ). 2021;19:184-189. doi:10.1176/appi.focus.20200045.
33. Adams TG, Brady RE, Lohr JM, Jacobs WJ. A meta-analysis of CBT components for anxiety disorders. Behav. Ther. 2015;38(4):87-97.
34. López-López JA, Davies SR, Caldwell DM, Churchill R, Peters TJ, Tallon D, et al. The process and delivery of CBT for depression in adults: A systematic review and network meta-analysis. Psychol Med. 2019;49(12):1937-1947. doi:10.1017/S003329171900120X.
35. Taylor A, Tallon D, Kessler D, Peters TJ, Shafran R, Williams C, Wiles N. An expert consensus on the most effective components of cognitive behavioural therapy for adults with depression: a modified Delphi study. Cogn Behav Ther. 2020 May;49(3):242-255. doi: 10.1080/16506073.2019.1641146.
36. Mayring P. Qualitative Content Analysis : A Step-by-Step Guide. London: Sage Publications, 2021.
37. Stangier U, Strauss B, Rief W, Hofmann SG. Prozessbasierte Therapie – ein Leitfaden. Unpublished manuscript. Goethe Universität Frankfurt; 2024.
38. Epskamp S, Cramer AOJ, Waldorp LJ, Schmittmann VD, Borsboom D. qgraph: Network visualizations of relationships in psychometric data. J Stat Softw. 2018;48(4):1-18. doi:10.18637/jss.v048.i04.
39. Stangier U, Strauß B, Rief W, Hofmann SG. Der prozessbasierte Ansatz in der Psychotherapie [The Process-based approach in psychotherapy]. Die Psychotherapie. 2024;69:15-23. doi:10.1007/s00278-023-00690-6.
40. Hayes SC, Hofmann SG, Wilson DS. Clinical psychology is an applied evolutionary science. Clin Psychol Rev. 2020;81:101892. doi:10.1016/j.cpr.2020.101892.
41. Wenzel A. Strategic decision making in cognitive behavioral therapy. American Psychological Association; 2013. doi:10.1037/14188-000.
42. Sim, J. Should treatment effects be estimated in pilot and feasibility studies?. Pilot Feasibility Stud 5, 107 (2019). https://doi.org/10.1186/s40814-019-0493-7
43. Billingham, S.A., Whitehead, A.L. & Julious, S.A. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC Med Res Methodol 13, 104 (2013). https://doi.org/10.1186/1471-2288-13-104

44. Lemey C, Larsen ME, Devylder J, Courtet P, Billot R, Lenca P, et al. Clinicians' Concerns About Mobile Ecological Momentary Assessment Tools Designed for Emerging Psychiatric Problems: Prospective Acceptability Assessment of the MEmind App. J Med Internet Res. 2019;21(4):e10111. doi:10.2196/10111.
45. Ellison WD. An Initial Study of Practicing Psychologists' Views of the Utility of Ecological Momentary Assessment for Difficult Psychotherapy Cases. Adm Policy Ment Health. 2021;48:597-607. doi:10.1007/s10488-020-01093-4.
46. Degroote L, DeSmet A, De Bourdeaudhuij I, Van Dyck D, Crombez G. Content validity and methodological considerations in ecological momentary assessment studies on physical activity and sedentary behaviour: a systematic review. Int J Behav Nutr Phys Act. 2020;17:1-13.
47. Hall M, Lappenbusch LM, Wiegmann E, Rubel JA. To use or not to use: Exploring therapists' experiences with pre-treatment EMA-based personalized feedback in the TheraNet project. Adm Policy Ment Health. [Internet]. 2024 [cited 2024 Jul 16]. Available from: doi:10.1007/s10488-023-01333-3.
48. Borsboom D. A network theory of mental disorders. World Psychiatry. 2017;16(1):5-13.
49. Hayes SC, Wilson KG, Gifford EV, Follette VM, Strosahl K. Experiential avoidance and behavioral disorders: A functional dimensional approach to diagnosis and treatment. J Consult Clin Psychol. 1996;64(6):1152-1168. doi:10.1037/0022-006X.64.6.1152.
50. Ciarrochi J, Hayes SC, Oades LG, Hofmann SG. Toward a Unified Framework for Positive Psychology Interventions: Evidence-Based Processes of Change in Coaching, Prevention, and Training. Front Psychol. 2022;12:809362. doi:10.3389/fpsyg.2021.809362.