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Feasibility of Process-based Therapy in a naturalistic setting: Study protocol for a randomized controlled trial

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Abstract

Background

In the naturalistic setting of mental health care, treatment decisions of psychotherapists are often based on theories or experience related to treatment approaches. An alternative approach to treatment decision is suggested by Process-based Therapy (PBT), which emphasizes empirical and rational criteria for selection of intervention. It utilizes ecological momentary assessment (EMA) data, incorporates feedback from dynamic network analysis, and supports interventions to be chosen based on 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 explore the acceptability and efficacy of PBT as compared to psychotherapy delivered in routine practice (r-PT).

Methods/design

The study is a randomized controlled trial (RCT) of PBT vs r-PT. 60 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 therapists. As indicators of feasibility, adherence with process-based treatment rationale, acceptance of treatment by therapists and patients, and attrition rate will be assessed. Primary outcome is patient-rated quality of life. Secondary outcomes include psychological well-being, psychological symptoms of distress, depressive and anxious symptoms, adaptive behavior, psychological flexibility, and reflective functioning. Assessments of outcome variables are conducted pre-, mid-, and post-treatment and at 6 months follow-up.

Discussion

The current study will be the first exploring the dissemination of PBT in a naturalistic mental health care setting. If feasibility of PBT is demonstrated, the results may give rise to new perspectives in the personalization of assessment and treatment based on dynamic network analysis of EMA and rationale treatment decision making.

Trial registration
Clinicaltrials.gov JWGUniversity record III III L5 - 519/05.000.002 - 2. Registered 01 August 2024

Background

In mental health care, a wide range of psychological treatments is available. A recent meta-analysis of uncontrolled studies of psychological interventions delivered in routine practice [1] showed that large pre-post effect sizes were achieved in the reduction of depression and anxiety. However, it remains unclear whether such positive effects can also be obtained in routine mental health care settings. An exception is the Improving Access to Psychological Therapies program in England which demonstrated that the implementation of stepped-care clinical guidelines may help to bridge the gap between evidence-based research and practice [2]. However, treatment guidelines usually provide only rough recommendations for evidence-based manuals for specific diagnoses, and it remains unclear how these 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 based on the therapist's personal experience or school-based treatment theories than on empirical evidence [3,4].

A promising approach to improve the outcomes of mental health care is personalization [5]. Personalization can be conceptualized is a process that involves a collaborative collection and processing of diagnostic information as well as shared decision-making in the treatment selection. Personalization refers to treatment related decisions which can be based on intuition and experience, theoretical models underlying the treatment concepts, algorithms using scientific evidence for effective interventions, or precise statistical models used to predict the outcome of specific interventions based on big data [5]. Preliminary results from randomized controlled trials indicate that the effectiveness of treatments may be increased by personalized treatments [6].

A key to personalize treatment is to refine the adaptation of interventions to the individual problem and from research on active ingredients [7]. 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 characterized by two principles [8]:

1. To identify the key process maintaining the maladaptive pattern by using ecological momentary assessment (EMA) and dynamic network analysis [9]
2. To select interventions according to scientific evidence for the ability to change this key process [10].

The process-based approach conceives 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 based on 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] propose that mental health problems can be conceptualized as an idiographic network of maladaptive psychological processes in a specific context, rather than symptoms of a static state of disease. Within this evolutionary framework, change processes in psychotherapy are guided by the principles of context-dependent variation, selection, and retention, modifying the elements of the maladaptive individual psychological network, and creating an adaptive, more flexible network.

To sum up, 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 into 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 by using EMA and dynamic network analysis, and 2) interventions are selected based on active ingredients fitting to the key factors of the individual problem [8]. In the proposed study, we examine the hypothesis whether of the diagnostic process and treatment selection as intended in process-based therapy is feasible for the implementation into clinical practice. Furthermore, we want to explore whether PBT is more effective than routine CBT. Since the principles of PBT are not related or even restricted to specific disorders, patients with a broad range of diagnoses will be included in the trial.

Objectives

The main objective is to explore the feasibility of PBT in a routine mental health care setting delivered by practitioners. Feasibility comprises acceptance, evaluation of utility, compliance of patient and adherence of therapists with the treatment. To determine the degree of feasibility, we compare patients' and therapists' ratings of feasibility related to PBT with ratings in routine psychotherapy.
The specific questions related to feasibility are:

- Is the credibility of PBT assessed before treatment reduced, as compared to the credibility of routine psychotherapy?
- Are patients after receiving PBT less satisfied with their treatment, as compared to r-PT?
- With regards to the PBT condition, what is the ratio of therapists and patients who report low vs. high utility of EMA and dynamic network models?
- How many therapists report low vs. high levels of acceptability, as defined by reasonableness, effectiveness, side effects, effort required, costs, and willingness to implement PBT in their usual practice?
- As another aspect of feasibility, we also assess compliance of patients with EMA and adherence of therapists with process-based decision-making, i.e. application of EMA, use of dynamic network analysis, and network-based implementation of interventions.

A secondary aim is to investigate the initial evidence for the effectiveness of PBT in clinical practice. For this purpose, the effects of PBT after EMA-Baseline, after treatment and at 6-month follow-up, as self-rated by patients, will be compared with psychological treatment as usual. The hypotheses related to effectiveness are:
PBT will be superior to r-PT after treatment and at 6-month follow-up with regard to:

- psychological distress
- quality of life
- psychological well-being
- changes in psychological flexibility
- adaptive behavior
- reflective functioning
- capacity for social and interpersonal pleasure

Furthermore, we will examine the patients' changes in avoidance/ behavioral control and cognitive style on outcome as a possible mediator. Our hypothesis is that PBT

will be associated with larger changes in avoidance/ behavioral control and cognitive style, and that these changes are significantly related to the primary outcome, i.e. psychological distress.

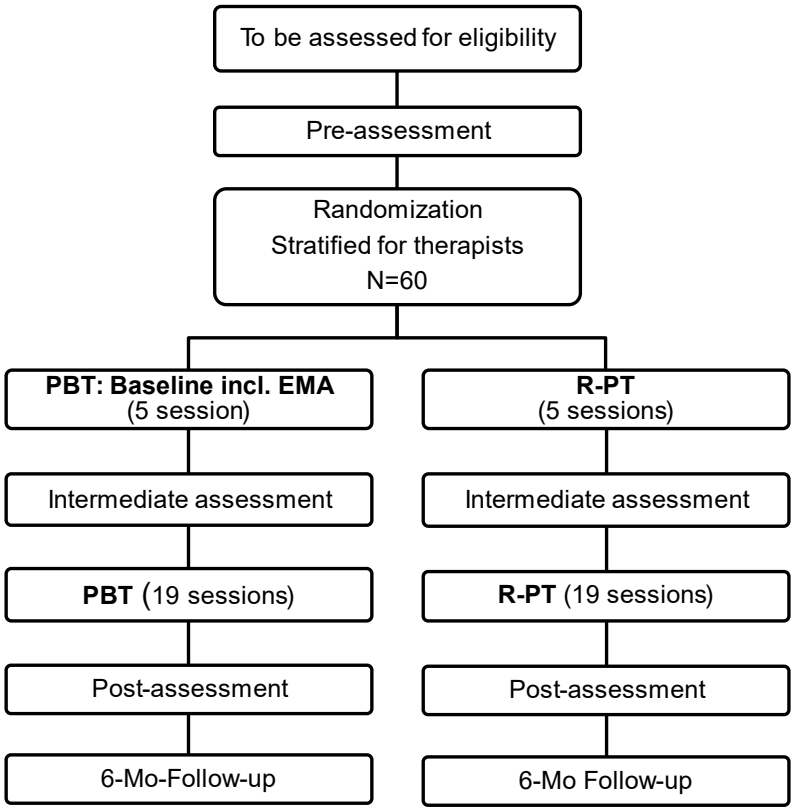
Finally, we will investigate potential moderators of outcome, i.e. patient expectations, and therapeutic alliance across and within treatment conditions, and therapists' adherence with the manual within the PBT condition.

Methods/design

Design

The current trial is an exploratory randomized controlled 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 both 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

Assessments of dependent variables are taken at four measurement points: before treatment, at mid-treatment, after treatment, and at 6-month follow-up (see. Table 1). The mid-treatment point is after session 5, to assess for changes due to EMA.

Indicators for feasibility will be assessed before and after treatment. Feasibility measures include both patients' and therapists' ratings of pre-treatment credibility and acceptance and attitude towards utility of EMA after treatment. Furthermore, we examine patients' compliance with EMA and therapists' adherence with process-based decision-making during treatment.

Primary endpoints of outcome are patients' self-ratings of emotional distress, secondary outcomes include psychological well-being, quality of life and mental health at post-intervention and at 6 months follow-up.

Process variables include Psychological Flexibility, Reflective Functioning, Adaptive Behavior and Cognitive Behavioral Therapy Skills at pre, intermediate and post-assessment and at follow-up. In addition, therapeutic relationship will be assessed at pre- and post-treatment.

Measurement Points		**Inclusion**	**Pre-Treatment**	**Baseline Phase**	**Inter-mediate**	**Treatment Phase**	**Post-Treatment**	**Follow Up**
Treatment Sessions				1-5		6-24		
Week / Instrument		0	1	2-7	8	9-27	28	51
Therapist	ICD-11 Diagnosis	**X**					**X**	**X**
	CGI		**X**				**X**	**X**
	CGI-I						**X**	**X**
	HAQ-11		**X**				**X**	
	FAMOS		**X**					
	Intervention Checklist						**X**	
	PBDMQ					every 4 weeks		
	TAUEN						**X**	
	CEQ		**X**					
	TEI						**X**	
Patient	DASS-10		**X**		**X**		**X**	**X**
	EQ-5D		**X**				**X**	**X**
	PMH		**X**				**X**	**X**
	AAQ-II		**X**		**X**		**X**	**X**
	RFQ		**X**		**X**		**X**	**X**
	PBAT		**X**		**X**		**X**	**X**
	CBTSQ		**X**		**X**		**X**	**X**
	EMA (PBT)			Daily (only PBT)			**X**	
	HAQ-11		**X**				**X**	
	CEQ		**X**					
	PAUEN						**X**	
	CSQ						**X**	

Table 1 Overview of measurements

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 towards utility of EMA and networks 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 attitude towards utility of EMA and networks Scale;
CSQ-8, Client Satisfaction Questionnaire

Measures

Feasibility

The primary outcome measure for feasibility is the Treatment Evaluation Inventory (TEI) [17]. It consists of 14 Items with a 7-point scale. The items are phrased as statements about the treatment, and respondents indicate their level of agreement or disagreement with each statement after the treatment.

Additionally, to assess the acceptance of treatment, treatment expectancy and credibility before treatment will be assessed using the Credibility/Expectancy Questionnaire (CEQ) [15]. Higher scores on the CEQ indicate better outcome expectations and greater perceived credibility of the treatment. The CEQ comprises 6 items with three items on each of the two subscales credibility and expectancy. Furthermore, the study includes the Patient attitude towards utility of EMA and networks scale (PAUEN) and the Therapists attitude towards utility of EMA and networks scale (TAUEN) which are modified versions of the Therapist and Client Attitude Measures by Frumkin et al. (2021) [16]. The scales have eight items in the patient version and six items for therapists that can both be answered on a five-point scale. The items are assessed post-treatment. Designed to measure satisfaction with health services, the Client Satisfaction Questionnaire (CSQ-8) [18] will be assessed at post treatment as well. It consists of eight self-report items.

Effectiveness

To assess psychological symptoms of distress, depressive and anxious symptoms, the short version of the Depression Anxiety Stress Scale (DASS-10) [21] will be used at pre-treatment, at mid-treatment, post-treatment and at 6-month follow-up. Additional outcome measures include the health-related quality of life will be evaluated using the Euroqol-5D (EQ-5D) [19] pre-treatment, post-treatment and at 6-month follow-up.

Furthermore, the Positive-Mental Health Scale (PMH) [20] is used to assess positive mental health pre-treatment and post-treatment including emotional, psychological, and social aspects of well-being by including 9 self-report items.
Psychological flexibility is measured by the Acceptance and Action Questionnaire Version 2 (AAQ-2) [22] on three self-report items. Furthermore, reflective functioning will be assessed by using the Reflective Functioning Questionnaire (RFQ-8) [23], a 54-item self-report inventory evaluating the capacity to comprehend internal mental states of oneself and others across two dimensions: Certainty and Uncertainty about mental states. Using the Process-based Assessment Tool (PBAT) [24] variation, selection and retention of adaptive behavior will be measured pre-treatment, at intermediate treatment, post-treatment and at the 6-month follow-up. The Cognitive-Behavioral-Therapy Skills Questionnaire (CBTSQ) [25] consisting of six self-report items measures patients' use of cognitive behavioral therapy interventions in the study.

Therapists' ratings

Diagnosis will be based on the ICD-11 and made by the therapists. Post treatment a check-list of interventions for therapists is implemented to verify adherence. The Process-based Decision-making Questionnaire (PBDMQ) [26] comprises 24 items designed to evaluate adherence to process-based therapy (PBT). The "Clinical Global Impression Scale" (CGI) [27] that 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 the therapists.

Moderators
Therapeutic alliance is assessed by patients and therapists by using the 11-item Helping Alliance Questionnaire (HAQ-11) [28].
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.

EMA
The Status-PBT (Vacay ©, 2024) is a mobile application for EMA during baseline phase which 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. 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 check-list of interventions for therapists is used after post-treatment assessment to check adherence, based on literature reviews [30,31] and meta-analyses [32-34].

Settings

Therapists participating in the trial are psychotherapists who are licensed for cognitive-behavioral therapy or psychodynamic psychotherapy for adult patients Therapists will be recruited in the Rhine-Main-Area and neighboring regions. All 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 [35] containing essential procedures in network-based assessment and treatment.

Participants

We aim to include 60 patients who meet the 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 to keep medication constant over the treatment period. Patients will be excluded in case of (1) increased suicidality, (2) substance abuse or dependency, (3) diagnose 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 intake clinicians using M.I.N.I. [36] adapted for DSM-5.

Recruitment and randomization procedure

Patients are evaluated by the therapists to be eligible for participation in the study based on inclusion and exclusion criteria described before. 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 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 to randomization is given, patient will be randomized to one of both 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 using the statistical software R. The group allocations are printed out 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.
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. Besides the definition of maladaptive responses, also the adaptive counterparts of the variables, representing the desired outcomes to be targeted in treatment, are 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 [37]. 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 session 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, 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 [38]. 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 [39]. 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 changing them, e.g. avoidance and exposure in anxiety disorder or reduced reinforcement of activities and behavioral activation in depression [40]. 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. Treatment process is largely structured by personal preferences of the therapist due to experience, knowledge, or recommendations of the National guidelines for the mental health problem.

Treatment fidelity

Adherence with PBT vs. r-PT treatment will be checked using 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.

Statistical analyses

Since it is not the primary goal of this trial to assess the efficacy of PBT, no power analysis is planned to determine the sample size. Furthermore, statistical analysis will be based on completed assessments, but not include intention-to-treat analysis. For exploratory mediator analyses, we will apply Cross-Lagged Modeling and Structural Equation Modeling [41].
Dynamic network analysis of EMA data at baseline and at post-treatment will be computed using the R package "graphical VAR" [37].

Ethics and governance

The protocol has been approved by the Ethics Committee at the Department of Psychology (Registration number: ###) Protocol amendments will be communicated at https://clinicaltrials.gov and detailed in publications.

Adverse events, in particular suicidal behavior/ideation, will be monitored. Withdrawal from the study will be considered in case of increased suicidal ideation or acute suicidality.

The first author, U.S. is principal investigator (PI) and initiated the project together with the senior author, S.G.H. The study does not have a data monitoring committee.

Discussion

The study will be the first investigating 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 which 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 which can be assessed in EMA. However, as some studies pointed out, practitioners are skeptical towards the application of digital assessment methods [16, 42, 43]. The technical requirements also must be given [44] which might limit application.

Second, the outcome of dynamic network analyses of EMA data is dependent on the quality of information covered in the smartphone-based assessments. Thus, the identification of relevant dimensions in the exploration is an important challenge in the initial sessions, before EMA is established during baseline. During the EMA phase, it is essential for users that it is understood 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 to organize treatment. The identification of parameters such as central nodes, positive and negative feedback circles, as well as 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 [45].

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 the 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 [46]. Therefore, selecting personalized interventions based on information about the dynamic network model are not yet 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' s life may not only be associated

with digital distress, but also requires to interrupt automatic habits and to focus on psychological dimensions as worked out in therapy. Thus, patients must refrain from avoiding negative emotions, face the problem and judge their reactions. Thus, the capacity to accept distressing internal experiences is necessary to overcome experiential avoidance [47]. On the other side, using bipolar ratings including positive dimensions may also motivate the patient to engage in change processes even before therapeutic strategies are applied [48].

This trial will give valuable insights into barriers to implement PBT, which helps to improve the conceptualization of decision processes in this new approach, as well as the training and supervision of therapists. However, with respect to effectiveness, design and setting of our study is 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 of routine psychotherapy. Therapists' competence in applying specific decision-making strategies in PBT, their adherence with 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 will be applied to control for these factors, it is difficult to estimate whether statistically significant differences can be achieved. Second, we did not include independent clinical judgements of primary outcome, due to problems in organizing the timing with practitioners. Thus, there will be a lack of objective information about treatment effects. Third, inclusion criteria are broadly defined and will allow for a heterogenous composition of the sample with respect to diagnoses and severity. Although patients are randomized to both treatment conditions within therapists, equivalence of subsamples with respect to clinical characteristics may be impaired.

Besides these limitations, the implementation in a natural setting of practicing psychotherapists with low interference with the therapeutic procedures ensures that the generalizability of the outcome on the broader target of mental health care. Furthermore, in addition to providing information on the outcome, the practical experiences of psychotherapists will also stimulate new ideas how to improve the conceptualization and implementation of PBT.

Trial status

Training of therapists and outcome assessors is ongoing and the study will continue until September 2025.

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