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Efficacy of a process-based, Mobile-delivered personalized CBT for anxiety disorders: Study protocol for a randomized controlled trial

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ABSTRACT

Background: Internet-based Cognitive Behavioral Therapy (ICBT) is effective in treating anxiety disorders, yet there is room for improvement in treatment response and reduction in dropout rates. This study proposes a personalized, modular ICBT intervention that leverages the extended evolutionary meta-model to provide a dynamic and adaptive treatment approach, aiming to enhance usability and efficacy.

Methods: The trial will be conducted in two phases. Phase I involves 182 participants who will undergo a 30-day ecological momentary assessment to record functional processes and anxiety levels three times a day. The data collected will help in identifying key functional predictors of anxiety for each participant through group iterative multiple model estimation. In Phase II, participants who complete Phase I will be randomized into three groups: personalized CBT, standard CBT, and a waiting list. Outcome measures will include Brief Symptom Inventory, specific measures of anxiety, usability metrics, and dropout rates. Assessments will be conducted at baseline, immediately post-treatment, and at 1- and 3-month follow-ups. A linear mixed model will be utilized to analyze the data and determine the intervention's efficacy.

Discussion: Anticipated outcomes from this study include advancements in personalized CBT for anxiety disorders, contributing valuable insights into their potential benefits and addressing existing challenges in the field.

1. Introduction

Anxiety disorders rank among the most prevalent mental health conditions, significantly impacting individuals and society at large (Stein et al., 2017). Recognized by the World Health Organization as the ninth most critical global health issue (Vos et al., 2017), anxiety disorders are diagnosed in 3.8 %–25 % adult populations (Remes et al., 2016). These disorders are characterized by symptoms such as excessive fear, nervous tension, and avoidance behaviors, along with autonomic dysfunctions like palpitations, dizziness, and insomnia. Such symptoms can severely impair physical, mental, and social functioning (Stein et al., 2017). Despite their widespread impact, many countries still allocate insufficient healthcare resources to effectively manage anxiety disorders (Whiteford et al., 2013).

1.1. Cognitive behavioral therapy (CBT) for anxiety disorders

CBT represents a comprehensive range of therapies and treatment components, fundamentally aimed at modifying maladaptive cognitive and behavioral patterns (Beck, 2020). It is highly recommended for managing anxiety disorders, a position supported by numerous studies (Kaczkurkin and Foa, 2015; Olatunji et al., 2010; Öst, 2008). The term CBT broadly encompasses various approaches including behavioral therapy, cognitive therapy, and third-generation therapies such as Acceptance and Commitment Therapy (ACT) and Mindfulness-Based Stress Reduction (MBSR). These methods share common intervention components yet possess unique treatment strategies that enhance their specific efficacy (Carona, 2023). Craske (2010) suggests that CBT should be viewed as an integrative term that encapsulates a spectrum of therapies, each characterized by a unique blend of intervention components and strategies. This perspective highlights the adaptability and comprehensive nature of CBT, establishing it as a fundamental aspect of

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psychotherapeutic practice.

Empirical research robustly supports the efficacy of CBT in treating anxiety, showing medium to large effects across a variety of diagnoses (J. K. Carpenter et al., 2018; Cuijpers et al., 2016). Recent advancements in technology have expanded the use of Internet-based CBT (ICBT) for anxiety disorders significantly. ICBT is not only cost-effective and convenient but also offers extensive accessibility, breaking through geographical and temporal barriers, thereby facilitating access for individuals unable to engage in traditional, in-person sessions (Gega et al., 2022). The effectiveness of ICBT is well-supported by empirical studies (Etzelmueller et al., 2020; Spek et al., 2007; vant Hof et al., 2009), and meta-analyses confirm that it matches the efficacy of face-to-face CBT without significant differences in outcomes (Esfandiari et al., 2021).

However, not all patients with anxiety disorders respond to ICBT (Bandelow et al., 2014). A systematic review indicated that the overall treatment response rate for ICBT across various psychological conditions is approximately 69.9 %, yet anxiety disorders exhibit significantly lower response rates compared to other mental health issues (Andersson et al., 2019). Furthermore, ICBT faces challenges with high dropout rates (Bados et al., 2007). A meta-analysis reported a general dropout rate of 26.2 % for CBT across mental health conditions, with the rate for ICBT rising to 34.2 % (Fernandez et al., 2015). These statistics underscore the considerable room for improvement in both the efficacy and retention rates in ICBT for anxiety disorders.

Traditional ICBT often relies on established pathological assumptions that apply the same treatment logic to all participants, employing a "one-size-fits-all" approach (Magill et al., 2023). This method may not adequately address the individual characteristics and specific needs of each person, potentially limiting its effectiveness. In contrast, personalized psychotherapy emphasizes a shift from group-focused treatments to individual-centric approaches, crafting treatment plans tailored to the unique needs of each person and embracing a "person-centered" intervention philosophy. This approach is currently at the forefront of research, offering new perspectives and innovations in psychotherapeutic treatment (Andrews and Williams, 2014; Ng and Weisz, 2016).

1.2. Process-based personalized psychotherapy

In the realm of personalized psychotherapy, a crucial question is which individual characteristics should be targeted for customization. Most research to date has concentrated on symptoms or clinical and demographic features as moderating variables to define the scope of "personalization," essentially addressing the question of "for whom" the treatment is designed (Thompson-Hollands et al., 2014). Traditionally, evidence-based psychotherapy has developed treatment plans based on symptoms or diagnoses, then tested these within various disease frameworks (Hofmann and Hayes, 2019). Unfortunately, such disease classification diagnoses often fail to provide substantial guidance for clinical treatments because, unlike physiological diseases, mental disorders cannot be targeted based on type alone (Hayes et al., 2020). Furthermore, while some studies have introduced other significant moderating variables, and even employed data-driven machine learning algorithms to select appropriate therapies or predict treatment outcomes and dropout rates(Aafjes-van Doorn et al., 2021), the variability and stability of these predictions remain concerns, as outcomes and predictive efficacy vary widely between studies (Schneider et al., 2015).

Focusing solely on syndromes and demographic features often falls short in providing a comprehensive understanding of therapeutic processes. Modern CBT approaches are sometimes criticized for their "black box" nature, where the specific procedures and processes that drive changes of outcomes remain obscured (Huibers et al., 2021). This critique underscores the need for a deeper personalization of treatment processes and the procedures influencing outcomes, an approach referred to as Process-Based Therapy (PBT) (Moskow et al., 2023).

The shift towards PBT marks a significant evolution in psychotherapy, moving away from a one-size-fits-all approach. By focusing on the

individual mechanisms of change, PBT aims to tailor interventions more precisely to individual needs, thereby increasing both the specificity and effectiveness of treatments. This innovative approach has attracted considerable attention and stimulated scholarly discussions, highlighting its potential to refine and improve psychotherapeutic interventions (Hayes et al., 2022; Hofmann and Hayes, 2019). These discussions emphasize the importance of understanding and implementing therapeutic processes that directly engage the specific needs and conditions of patients, rather than applying generalized treatments.

The ongoing shift towards process-based, personalized CBT in addressing anxiety disorders is compelling, yet it poses the significant challenge of assessing each individual's unique functional processes. The Extended Evolutionary Meta-Model (EEMM) offers a comprehensive framework that identifies core psychological processes—such as cognition, affect, attention, motivation, self, and overt behavior—shaped by evolutionary principles. These processes manifest across sociocultural and genetic/physiological levels, demanding a nuanced approach to therapeutic interventions(Hayes and Hofmann, 2020; Hofmann and Hayes, 2019).

This model has been instrumental in guiding the selection of therapeutic modules tailored to the individual's pathological processes, integrating various CBT techniques to form a cohesive treatment strategy. The evolution of internet technologies further enhances this approach, facilitating the development of personalized, internet-based CBT that adapts to the specific needs of the individual (Hayes et al., 2020). A critical component of this approach involves the Process Based Assessment Tool (PBAT), which measures a broad spectrum of psychological aspects (Ciarrochi et al., 2022).

1.3. Idiographic approaches for process-based personalized psychotherapy

PBT and EEMM provide a robust theoretical framework for processbased personalized psychotherapy, which emphasizes the individual variability in psychopathology and the need for tailored interventions. To address the intricacies of personalized psychopathology and psychotherapy, an idiographic research methodology is essential. Traditional nomothetic approaches, while aiming to identify universal principles applicable to groups, often fail to capture the complex associations between psychological processes and outcomes that can vary significantly across individuals over time (Molenaar, 2004). Research has consistently shown that findings at the individual level can diverge substantially from aggregated group data, underscoring the limitations of broad generalizations in understanding personal psychopathology (Boswell et al., 2014; Bringmann et al., 2013; Ellison et al., 2020; Howe et al., 2020). Consequently, it has been argued that researchers should employ person-specific methodologies, in order to understand the dynamic interplay of functional processes and mental states at an individual level (Fisher, 2015).

The advancement of idiographic methodologies is intrinsically linked to innovations in data collection and analytical techniques. The introduction of Ecological Momentary Assessment (EMA), an approach to intensive longitudinal data sampling, has equipped researchers with comprehensive multivariate dynamic data, facilitating the construction of individualized models(Shiffman et al., 2008). EMA specializes in capturing real-time, multi-location data within natural settings, significantly reducing memory biases and bolstering ecological validity (Ebner-Priemer and Trull, 2009; Moskowitz and Young, 2006). This technique requires regular measurements, yielding data at multiple time points, which is crucial for examining the progression and interactions of internal psychological variables over time (R. W. Carpenter et al., 2016). Moreover, the widespread adoption of smart devices has streamlined the implementation and enhanced the practicality of EMA (Conner and Mehl, 2015; Trull and Ebner-Priemer, 2014).

Idiographic analyses employing network theory robustly support the exploration of personalized pathology and interventions. The network

approach conceptualizes psychological syndromes and functional processes as interconnected constructs that mutually influence and reinforce each other over time (Borsboom and Cramer, 2013). In a dynamic network (refer to Fig. 1 for an illustration), nodes represent various features of psychopathology and symptoms, while directed edges denote partial regression coefficients that illustrate the relationships between different nodes. Such temporal network structure leverages intensive time-series data to offer insights into potential Granger causality, thereby informing targeted treatment strategies (Epskamp et al., 2018).

Recent empirical research has investigated the effectiveness of customized treatments utilizing EMA and idiographic analyses, yielding promising results. A randomized controlled (RCT) trial by Levin et al. (2019) demonstrated that participants using an Acceptance and Commitment Therapy (ACT) application, which provided skill coaching tailored to real-time EMA data, exhibited significant improvements in psychological distress and mental health compared to those using a standard app or EMA alone. Similarly, Fisher et al. (2019) gathered EMA data from individuals exhibiting symptoms indicative of Generalized Anxiety Disorder (GAD) and Major Depression Disorder. They applied

person-specific dynamic factor analyses to customize modules of CBT and assessed its effectiveness in an open trial. Significant improvements were observed in the following open trial, in support of personalization, modularization, and idiographic research paradigms. The trial revealed substantial enhancements, affirming the benefits of personalized, modular, and idiographic approaches to treatment. However, it is important to note that these studies did not utilize a process-based personalized treatment framework as outlined in the EEMM.

Sanford (2022) employed a daily measurement approach alongside idiographic network analyses in his study to examine the intricate interactions among various psychological processes detailed in the EEMM and symptoms such as anxiety and emotional exhaustion. This method helped in identifying both individual and subgroup patterns, shedding light on how different processes interplay uniquely across different groups and individuals.

The insights gained from this research can be poised to guide the development of targeted CBT modules, which will be customized for delivery through internet-based platforms. This approach emphasizes a move towards more personalized and nuanced treatments, specifically

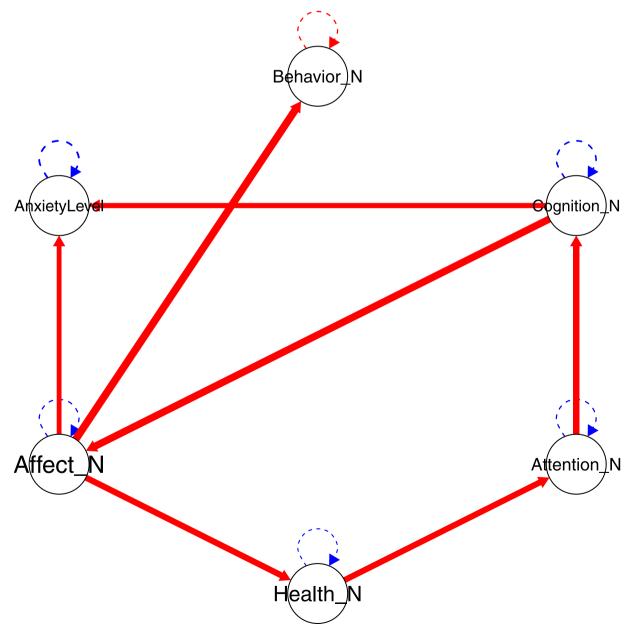


Fig. 1. An example of a temporal network graph based on an individual's time-series data.

designed to address the unique psychopathological needs of individuals, with the potential to enhance the overall effectiveness of interventions. To validate and further assess the efficacy of these innovative, process-based, mobile-delivered interventions, a RCT is proposed in the present protocol. This step is crucial in establishing the practical viability and impact of such personalized therapeutic strategies in real-world settings.

2. Method

2.1. Study design

This study will employ a two-phase clinical trial approach to investigate the efficacy of a process-based personalized ICBT in treating anxiety disorders (Fig. 2, Table 1). The study design has been approved by the Ethics Committee of Central China Normal University (CCNU-IRB-202306015b). Furthermore, the trial will be registered with the Chinese Clinical Trial Registry (https://www.chictr.org.cn/) prior to the initiation of the study. Personal information will be securely collected, stored, and shared in compliance with data protection regulations to ensure confidentiality throughout the trial.

2.1.1. Phase I: EMA self-monitoring

Participants will initially complete an online screening questionnaire followed by a clinical diagnostic interview based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria. Those diagnosed with Generalized Anxiety Disorder (GAD), Panic Disorder (PD), or Social Anxiety Disorder (SAD) will engage in self-monitoring of their functional processes and anxiety symptoms three times daily for 30 days via the internet. This phase will utilize Group Iterative Multiple Model Estimation (GIMME) analysis on the EMA data to determine the relationship between each participant's functional processes and their anxiety symptoms, identifying specific maladaptive functional processes.

2.1.2. Phase II: Randomized controlled trial

Participants who complete Phase I will be randomized into one of three groups: a standard CBT group, a personalized CBT group, and a wait-list group. The standard CBT group will undergo all the prescribed CBT treatment modules, while the personalized CBT group will receive modules tailored according to the results from the GIMME analysis. The wait-list group will not receive any intervention during this phase. Immediate post-treatment assessments will be conducted following the interventions. The standard CBT and wait-list groups will follow a 10-week treatment cycle, whereas the personalized CBT group's treatment duration may vary. Follow-up assessments will be conducted at 1 and 3 months post-treatment to evaluate long-term efficacy and stability of the treatment outcomes.

2.2. Participants

2.2.1. Sample size

The GIMME analysis allows for flexibility in sample size as it constructs a unique model for each participant (Luo et al., 2023). However, for a valid analysis, it is essential that each participant provides at least 75 usable data points (Mansueto et al., 2023). Participants failing to meet this criterion will be excluded from the GIMME analysis and subsequently from the RCT.

For Phase II, only participants who successfully complete Phase I will be considered. To determine the necessary sample size for detecting a moderate effect size (Cohen's d=0.5) with an alpha level of 0.05 and a power of 0.85, an a priori power analysis was conducted using G*Power 3.1. This analysis involved comparing three independent group means using two-tailed tests within the ANOVA framework for "Repeated measures, between factors" (Faul et al., 2009). The results indicated a requirement for 108 participants. Considering an expected dropout rate of 35.8 % for internet-based CBT and 5.8 % for ecological momentary

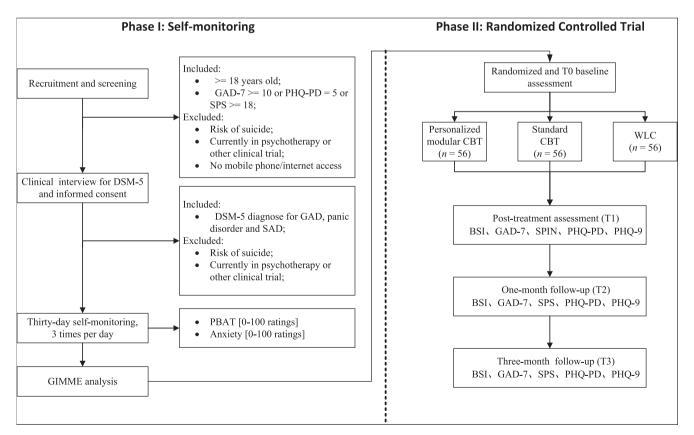


Fig. 2. Flowchart of the study design

Note. GIMME: Group Iterative Multiple Model Estimation; CBT: Cognitive Behavioral Therapy; WL: Wait-List; BSI: Brief Symptom Inventory; SPIN: Social Phobia Inventory; GAD-7: Generalized Anxiety Disorder Scale; PHQ-PD: Patient Health Questionnaire-Panic Disorder; PHQ-9: Patient Health Questionnaire-9;

Table 1
Content for the schedule of enrolment, intervention, and assessments.

_	Pre-Intervention				Post-Intervention			
Timepoint	Enrolment	EMA (30 days)	Baseline data (T1)	Allocation	Intervention	Post-Intervention (T0)	1-month Follow-up (T1)	3-month Follow-up (T2)
Enrolment								
Eligibility screen	X							
Initial interview	X							
Informed consent	X							
Allocation				X				
Interventions								
Standard CBT					X			
Personalized CBT					X			
WL								
Assessment								
Demographic	X							
characteristics								
PBAT		X						
Anxiety-2		X						
BSI-18			X			X	X	X
GAD-7	X		X			X	X	X
SPS	X		X			X	X	X
PHQ-PD	X		X			X	X	X
PHQ-9	X		X			X	X	X

Note. EMA: Ecological Momentary Assessment; CBT: Cognitive Behavioral Therapy; WL: Wait-List; PBAT: Process-based Assessment Tool; BSI: Brief Symptom Inventory; SPIN: Social Phobia Inventory; GAD-7: Generalized Anxiety Disorder Scale; PHQ-PD: Patient Health Questionnaire-Panic Disorder; PHQ-9: Patient Health Questionnaire-9;

assessment (Sanford et al., 2022a), the total sample size has been adjusted to at least 179 participants to ensure sufficient power for meaningful analysis.

2.2.2. Inclusion and exclusion criteria

Inclusion Criteria: Participants considered for this study must:

- ◆ Be at least 18 years old.
- ◆ Meet at least one Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criterion for Generalized Anxiety Disorder (GAD), Social Anxiety Disorder (SAD), or Panic Disorder (PD).
- Possess a mobile device capable of receiving and sending data for the purpose of ecological momentary assessment.
- Have maintained a stable dosage of any psychiatric medications for at least two months prior to the commencement of the study.

Exclusion Criteria: Participants will be excluded from the study if they:

- Are at risk of suicide, as determined by preliminary screening or clinical assessment.
- Are currently receiving psychological therapy or participating in other clinical research studies that could influence the outcomes of this trial.

2.3. Recruitment, randomization and blinding

2.3.1. Recruitment

Participants will be recruited through targeted advertisements on the internet and social media platforms. Interested individuals will be provided with an informed consent form, which will outline the study procedures, confidentiality measures, potential risks, and benefits. They will then be directed to engage with the study by scanning a QR code or clicking on a web link hosted by Questionnaire Star (www.wjx.cn), where they will complete a self-reported screening questionnaire. This questionnaire will gather demographic data, assess symptoms of anxiety (using the Generalized Anxiety Disorder 7-item scale, GAD-7; the Social Phobia Scale, SPS; and the Patient Health Questionnaire for Panic Disorder, PHQ-PD), and collect information on any existing mental disorder

diagnoses and current treatment statuses.

2.3.2. Eligibility assessment

Participants who meet at least one of the specified measurement cutoffs (GAD-7 \geq 10, SPS > 34, or PHQ-PD = 5) alongside other inclusion criteria will proceed to a clinical interview conducted via the internet by a professional clinical psychologist. Those who meet the DSM-5 criteria for GAD, PD or SAD during this interview will be eligible to participate in Phase I of the study.

2.3.3. Randomization and blinding

Following Phase I, eligible participants will be randomly assigned to one of three groups: the standard CBT intervention group, the personalized CBT intervention group, or a wait-list (WL) control group. Randomization will be carried out using the RESEARCH RANDOMIZER service (https://www.randomizer.org/), which will generate a random sequence for the three intervention groups. This method ensures that the allocation of participants to intervention groups is completely unbiased and random.

2.4. Interventions

2.4.1. Standard CBT group

Utilizing the EEMM, we have reorganized the key CBT modules for anxiety disorders. The standard CBT group will engage in all the intervention modules as outlined in Table 2. The treatment consists of 10 comprehensive modules, each including multiple sessions designed to target specific aspects of anxiety management: (1) Psychoeducation and allowing participants to set their own intervention goals; (2) Techniques for emotion identification, relaxation, and acceptance; (3) Strategies to reduce maladaptive attention patterns such as rumination and excessive worry; (4) Identifying and restructuring maladaptive cognitive patterns; (5) Enhancing self-esteem, self-efficacy, and self-compassion; (6) Clarifying values, committing to action, and enhancing motivation; (7) Learning and applying exposure techniques and problem-solving skills; (8) Developing social support networks and interpersonal skills; (9) Managing sleep, exercise, and dietary habits to support mental health; and (10) Strategies to maintain gains and prevent relapse.

Each module will include homework assignments to reinforce the lessons learned in sessions. Participants will have access to a therapist

Table 2
CBT modules and sessions within the EEMM framework.

	Module	Session
1	Introduction	Psycho-education;
		Setting goals;
2	Affect	Coping and emotion regulation;
		Breath retaining;
		Applied muscle relaxation;
		Mindfulness and acceptance;
3	Attention	Attention training;
		Mindfulness;
		Reducing self-focus;
4	Cognition	Cognitive defusion
		Cognitive reframing
5	Self	Self-esteem;
		Self-efficacy;
		Self-compassion;
6	Motivation	Норе;
		Value;
		Committed action;
7	Overt Behaviors	Safety behaviors;
		Exposure;
		Problem-solving;
8	Interpersonal Relationship	Social support;
		Social skills training;
9	Lifestyles	Sleep;
		Diet;
		Exercise
10	Relapse prevention	Maintain gains;
		Preventing relapse;

via a dedicated mailbox, where the therapist will provide answers to questions and feedback within three days, ensuring timely support throughout the treatment process. There will be no additional contact between the therapist and the participants outside of these structured interactions.

Each intervention session is designed to be concise, lasting approximately 10–15 min, with one session scheduled every three days. Participants must complete each session in sequence, unlocking the next session only after completing the previous one; notifications for new sessions will be sent via a public account message. To complete the entire intervention, participants will need a minimum of 10 weeks. This structured timeline ensures adequate exposure to all therapeutic components and allows for meaningful engagement with the treatment process.

2.4.2. Personalized CBT

Participants will engage in a personalized CBT program based on the idiographic network models generated using data from the EMA conducted in Phase I. These network models, created using the GIMME statistical approach, will provide a comprehensive understanding of the temporal and contemporaneous relationships between various psychological processes and the outcome of interest, anxiety. The network models will include directional associations that highlight the upstream functional processes that contribute to anxiety, allowing for targeted interventions at these nodes.

The principal investigator will input each participant's specific network model into the intervention application, selecting the appropriate modules tailored to the individual's needs based on the identified nodes. All participants will start with the psychoeducation module and conclude with the relapse prevention module—two fixed components to ensure a consistent foundational and concluding experience. The remaining modules will be dynamically assigned based on each participant's unique network structure, ensuring that interventions are personalized and relevant to the specific psychological processes influencing their anxiety.

Sessions will be scheduled every three days, with each new session unlocked only after the previous one is completed. The total duration of the intervention will depend on the number of personalized modules

assigned to each participant, allowing for an adaptive and flexible treatment approach. This methodology ensures that the intervention remains aligned with each individual's therapeutic needs, based on the personalized insights provided by the network model.

2.4.3. Wait-list control group

Participants in the WL group will not receive any active intervention during the study period. However, they will be required to complete regular assessments identical to those undertaken by the intervention groups. These assessments are crucial for maintaining a consistent data collection framework across all study groups, facilitating a comparative analysis of outcomes at the end of the study. This approach ensures that the wait-list group serves as an effective control for gauging the impact of the active interventions.

2.5. Assessments

This study will be conducted in China and all interactions with participants—including assessments and interventions—are conducted in Chinese. While most of the assessment tools and intervention materials used in this study are originally in English, validated Chinese versions are available for most instruments except the PBAT scale. For the PBAT scale, a rigorous translation and back-translation process is employed to ensure the accuracy and reliability of the Chinese version. This process involves translating the scale into Chinese by a bilingual expert, followed by an independent back-translation into English to check for consistency. Additionally, a pilot survey will be conducted to validate the reliability and validity of the translated instruments before their use in the study.

2.5.1. Ecological momentary assessment

Participants eligible for this study will utilize a specifically developed mini-app, designed to support EMA with integrated daily reminders. This tool is pivotal in capturing real-time, ecologically valid data from participants, reflecting their most immediate experiences.

Daily assessments are scheduled at three strategic times to capture a broad range of experiences throughout the day:

◆ Morning Window: 10:00 AM to 12:00 AM
◆ Afternoon Window: 16:00 PM to 18:00 PM
◆ Evening Window: 22:00 PM to midnight

These windows are carefully chosen to prevent overlap and ensure that data collected are specific to different periods of the day. Access to the assessment function will be restricted to these times, with the app automatically locking outside these hours.

To facilitate compliance and timely data entry, the app will send automatic reminders at the start of each assessment window. Once an assessment for a specific time slot is completed, the app will lock, preventing further entries until the next designated period. The content of EMA will be as follows.

2.5.1.1. Process-based Assessment Tool (PBAT) (Ciarrochi et al., 2022).

The PBAT a process measurement tool developed within the EEMM framework. It consists of 18 items that measure dimensions including affect, cognition, attention, motivation, overt behavior, physiological health, social connections, change, and maintenance. Each dimension includes both a positive and a negative item. Each item will be scored on a scale from 0 to 100 (0 = strongly disagree, 100 = strongly agree). This scale is suitable for EMA, and time prefixes can be added according to the measurement interval (Ciarrochi et al., 2022). In this study, assessments will capture participants' experiences during different parts of the day. Therefore, each item will include the appropriate prefix, such as 'In the morning,' 'In the afternoon,' or 'In the evening,' depending on the measurement time.

2.5.1.2. Anxiety. In the ecological momentary assessment, a single item will be used to measure the individuals' state of anxiety (Sanford et al., 2022b; Young et al., 2015). The items will be, 'In the morning/afternoon/night, I feel anxious or nervous.' Responses will be captured using a 0–100 sliding scale, where 0 indicates 'strongly disagree' and 100 indicates 'strongly agree.' Participants will be able to slide to select their response.

2.5.2. Outcomes for phase II

2.5.2.1. Brief symptom inventory 18 (BSI-18). The BSI-18 is a concise psychological assessment tool comprising 18 items, designed specifically to measure psychological distress in individuals (Derogatis, 2017). It assesses three primary symptom dimensions—somatization, anxiety, and depression—and also calculates a Global Severity Index (GSI), which provides an overall measure of psychological distress severity. Patients are asked to rate their level of distress over the past week for each of the 18 symptoms using a 5-point Likert-type scale that ranges from 0 (not at all) to 4 (extremely).

2.5.2.2. Generalized anxiety disorder (GAD-7). The GAD-7 (Spitzer et al., 2006) includes seven items covering core symptoms of generalized anxiety disorder, such as excessive worry, difficulty controlling anxiety, and restlessness. Each item has four response options, corresponding to different frequencies of symptoms, ranging from "not at all" to "nearly every day," scored from 0 to 3. The total score range for the GAD-7 is 0–21, with a clinical cutoff of 10 (Williams, 2014).

2.5.2.3. Social phobia inventory (SPIN). The SPIN is a scale designed for the screening and measurement of social anxiety disorder (Antony et al., 2006). the instrument consists of 17 items that assess fear, avoidance, and physiological discomfort in social or performance situations. Each item on the SPIN is scored on a scale from 0 (not at all) to 4 (extremely), allowing individuals to quantify the severity of their social anxiety symptoms over the past week. A cut-off of 19 is used to distinguish between clients with and without social phobia (Ranta et al., 2007).

2.5.2.4. Patient health questionnaire for panic disorder (PHQ-PD). The PHQ-PD includes five items, with the fifth item containing nine subitems to assess core symptoms of panic disorder, such as sudden panic attacks, palpitations, sweating, and difficulty breathing (Osório et al., 2015). Each item has two response options, "yes" and "no." For the first four items, a "yes" response scores 1 point, and a "no" response scores 0 points. The fifth item scores 1 point if at least four sub-items are answered "yes"; otherwise, it scores 0 points.

2.5.2.5. Patient health questionnaire (PHQ-9). The PHQ-9 is a widely used tool for assessing the level of depression in individuals (Kocalevent et al., 2013). It consists of 9 items that participants respond to their feelings and experiences over the past two weeks. Each item is scored on a scale from 0 to 3, where 0 means "not at all" and 3 means "nearly every day." The total possible score on the PHQ-9 ranges from 0 to 27. Scores between 10 and 19 suggest moderate depression, while scores of 20 and above indicate the possibility of severe depression. This scale is valuable in both clinical and research settings for diagnosing depression and monitoring treatment response (Manea et al., 2012).

2.6. Safety protocol

To ensure the safety of participants during Phase I and Phase II, we will exclude individuals with significant physical, suicidal, or cognitive risks that might compromise safety or the ability to participate in the study. Adverse events (AEs), as defined by Klatte et al. (2023), include any negative changes in physical or mental health, or significant changes in social or professional settings, as reported by the participant,

or observed by therapists. AEs will be monitored weekly by asking participants if they have experienced major health changes. Additionally, the Clinical Global Impression of Severity Scale (CGI—S) and a suicide risk assessment will be administered biweekly from baseline until treatment ends. Participants showing a CGI-I score of 5 or higher at any point will receive weekly assessments from a study clinician. If a participant shows major worsening symptoms or significant suicidal ideation consistently over two weeks, referrals will be made to ensure they receive care from certified mental health professionals.

2.7. Data management

2.7.1. Phase I: Group iterative multiple model estimation

The data from the EMA will be analyzed using GIMME. The analysis will be conducted using the gimme statistical package in R (Gates et al., 2017). The analysis will be performed in the R 4.0.2 environment (R Core Team, 2013). Following the recommendations of Mansueto et al. (2023), for accurate estimation of temporal global structures with 75 to 100 data points, it is advisable to limit the model to approximately six variables or nodes. Given that the PBAT consists of 18 items, we will treat anxiety as a fixed node and include a maximum of five additional nodes in each analysis. Multiple GIMME analyses will be conducted to explore the associations between all functional processes and anxiety. Each participant's data will be presented as a separate data matrix file, with column names representing variables and row indices representing different measurement time points. Current methodologies for managing missing data in individual time series designs vary, with no established consensus on the optimal approach (Honaker and King, 2010). GIMME will utilize the full information maximum likelihood (FIML) method to address any missing data issues. This approach uses all available data points to estimate model parameters, thereby avoiding the need for data imputation and allowing for the use of all observed data despite the presence of missing values.

GIMME integrates structural equation modeling (SEM) and vector autoregression (VAR) to estimate both contemporaneous and lagged relationships between variables, making it particularly suitable for developing individual-level causal models. This methodology does not assume homogeneity among participants, allowing for the exploration of unique causal paths for each individual. It achieves this by generating a distinctive network graph for each participant, illustrating the interconnections among relevant variables over time. This enables the model to reveal how variables influence each other linearly within and across time points. The mathematical representation of GIMME is as follows:

$$\eta_i(t) = (A_i + A^g)\eta_i(t) + (\Phi_{1,i} + \Phi_1^g)\eta_i(t-1) + \xi_i(t)$$

Where:

- \bullet $\eta i(t)$ denotes the p-dimensional time series at time point t,
- A and Φ represent the current and lagged relationship matrices, respectively,
- $igoplus \zeta_i$ is the p-dimensional error matrix,
- Superscript g denotes group-level relationships, and subscript i indicates individual-level relationships.

GIMME utilizes a specialized fitting procedure combining Lagrange multiplier testing and Wald trimming to ensure the results are consistent with the likelihood ratio test (Chou and Bentler, 1990). GIMME has two essential data assumptions that must be met: first, the solution for each participant (encompassing both group-level and individual-level relationships) is unique; there is no other network equally suited to the data. However, this may not always hold true because the *A* matrix, which represents the current relationship matrix, is essentially an embedded cross-sectional path model within GIMME, and multiple solutions in cross-sectional path models are characteristic (MacCallum

et al., 1993). To address potential issues with multiple solutions, GIMME for multiple solutions (GIMME-MS) is employed, generating network graphs for each participant using various potential solutions (Beltz and Molenaar, 2016). These graphs facilitate the identification of the functional processes most closely associated with anxiety symptoms, tailoring the analysis to the nuanced needs of each participant.

2.7.2. Phase II: Mixed model effects

The outcome for Phase II will be the degree of improvement. All collected data will be analyzed under the intention-to-treat (ITT) principle, ensuring that every participant who was randomized, including those who dropped out, is accounted for in the analysis. Mixed-effects models, as recommended by Gueorguieva and Krystal (2004), will be employed instead of traditional analysis of variance (ANOVA). These models are particularly advantageous for handling repeated measures data, offering the flexibility to model time-varying predictors, manage dependencies among repeated observations, and accommodate missing data using maximum likelihood estimation under non-restrictive missing data assumptions (Hesser, 2015).

Effect sizes will be presented using Cohen's d, where Cohen's d represents the difference between two group means divided by the pooled standard deviation. Effect sizes of 0.2–0.5 will be considered small, 0.5–0.8 as medium, and above 0.8 as large. Within-group effect sizes will be calculated based on the pooled standard deviation from pre- and posttests. Statistical power tests will be conducted based on comparisons between the intervention group and the self-monitoring group. With 80 % statistical power to detect an effect size of d=0.50, the sample size for this study will be statistically powered ($\alpha=0.05$).

To determine whether an individual responds to the intervention, the Reliable Change Index (RCI) will be utilized (Blampied, 2022). The index, based on the work of Jacobson and Truax (1992), standardizes the scale, where scores above the mean 1.96 indicate reliable improvement, scores below the mean — 1.96 indicate reliable deterioration, and scores in between indicate no change. RCI analysis will be conducted using the R package JTRCI, available at JTRCI GitHub (https://github.com/AWKruijt/JT-RCI).

2.8. Protocol modifications

This study is conducted under Protocol Version2, dated December 15, 2024. Each version is uniquely identified to track changes and updates throughout the research period effectively. The trial results will be communicated to participants, healthcare professionals, and the public through publication in peer-reviewed journals, reporting in clinical trial registries, and sharing through other relevant platforms.

In the event of any important protocol modifications, such as changes to eligibility criteria, outcomes, or analyses, the following steps will be taken:

- 1) Investigators will be promptly informed via email and meetings.
- 2) Ethics Committee (REC/IRB) will review and approve any changes before implementation.
- Trial Participants will be notified of relevant modifications during meetings or via email.
- Clinical Trial Registry will be updated to reflect any protocol changes.
- 5) Journals and Regulatory Bodies will be informed as necessary to ensure compliance.

3. Discussion

This protocol outlines a pioneering approach that leverages personalized psychopathology to refine CBT for anxiety disorders. Despite some consistency in functional processes of anxiety at the subgroup level, substantial individual variations exist. This variability underscores the necessity for clinical interventions that are precisely

tailored to maximize therapeutic efficacy.

CBT, widely acknowledged as the primary psychotherapy for anxiety disorders, encompasses a variety of therapies and techniques, each targeting specific psychological processes (McMain et al., 2015). The challenge lies in effectively aligning these diverse therapeutic components with the unique functional processes of each individual, a task that has sparked extensive discussion and is crucial for advancing personalized treatment strategies. The integration of the EEMM with CBT represents a novel effort to address this challenge. By assessing its applicability among individuals with anxiety from the perspective of individual differences, this study aims to advance the development of personalized psychopathology.

Furthermore, the protocol introduces a process-based, personalized networked CBT intervention model. This new framework for online psychological interventions emphasizes 'process-guidance' and 'personalization', transforming the conventional 'black box' or 'one-size-fits-all' approach of CBT into a dynamic, tailored treatment process (Hayes and Hofmann, 2020). The networked CBT application developed in this study is designed to deliver more targeted interventions, potentially enhancing responsiveness and reducing dropout rates by adjusting the intervention period to fit individual needs better.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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