Trials

STUDY PROTOCOL

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OutProFeed-Italy: a cluster randomized controlled trial of routine outcome monitoring and feedback-informed psychotherapy for outpatients

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Abstract

Background Routine outcome monitoring (ROM) with timely feedback to therapists may improve psychotherapy outcomes. OutProFeed-Italy is a protocol for a three-arm cluster randomized controlled trial (RCT) using a Zelen design to test whether feedback-informed therapy (FIT) delivered through a digital platform (Mindy) improves patient outcomes and therapeutic processes in routine outpatient psychotherapy in Italy.

Methods The study will recruit psychotherapy trainees and licensed psychotherapists practicing in Italy (licensed psychotherapists or trainees in ≥3rd year of an Italian Ministry of University and Research-recognized psychotherapy program) and their adult outpatients (≥18 years, with fewer than three sessions with the participating therapist; excluding psychotic and neurocognitive disorders). Therapists will be recruited by the research team through universities and professional networks, and each therapist will recruit 2–5 eligible patients from routine outpatient practice. Therapists (clusters) will be randomized 1:1:1 by an independent statistician to three conditions: (1) outcome and process monitoring only (OPM), with session-by-session measures results of which are displayed to therapists but without feedback with clinical support tools (CST); (2) outcome and process monitoring plus feedback (OPM-F), in which therapists receive feedback through Mindy's clinical support tools based on FIT principles, together with monthly supervision for 3 months; and (3) treatment as usual (TAU), with no monitoring or feedback, and assessments only at baseline, session 15, and 3-month follow-up. The planned sample size is 182 therapists (61 per arm) and approximately 546 patients. The primary outcomes are symptom severity from baseline to session 15 and 3-month follow-up; secondary outcomes include psychological distress, therapeutic alliance, and dropout rates. Safety will be monitored through repeated symptom and risk assessments and the recording of adverse events and withdrawals, with referral procedures as needed. First enrollment started in November 2024.

Discussion We hypothesize that, compared with OPM and TAU, patients treated by therapists in the OPM-F condition will show greater symptom improvement, fewer dropouts, and better therapeutic alliance trajectories. Findings may inform the implementation of ROM and FIT supported by digital platforms in Italian routine care.

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Keywords Feedback-informed therapy (FIT), Routine outcome monitoring (ROM), OutProFeed-Italy, Therapeutic alliance, Mindy

Introduction

Although there is strong evidence for the effectiveness of psychotherapy, not all patients improve, and a proportion of patients may get worse [1]. Prevention of treatment failures is an important goal of clinical practice [2]. Researchers have shown that monitoring patient change on a session-by-session basis can be effective to inform treatment decisions, especially for patients who do not report improvement and are at risk of dropping out [3].

Routine outcome monitoring (ROM) is a promising procedure for tracking patient change in routine clinical practice and can effectively provide feedback to therapists [4] to enhance treatment outcomes [5]. ROM includes three sequential phases [6]: (i) collecting patient data regularly and in a structured manner; (ii) providing data to the therapist and often to the patient; and (iii) when appropriate, encouraging therapists to adjust the treatment process or focus based on the emerging feedback. These three phases have been presented as a transtheoretical model of measurement-based care—Collect, Share, Act [7]. Providing progress feedback to therapists can help to alert a therapist when a patient is progressing as expected (On Track cases) or worsening (Not on Track cases), and to adjust the treatment for Not on Track cases [8]. ROM has been presented as a "*relatively simple evidence-based practice… that clinicians can add to any type of psychotherapy… without requiring changes to that psychotherapy*" [9].

The American Psychological Association (APA) has long recommended the use of ROM and feedback in routine care [10]. A recent advisory committee appointed by the APA governance has advocated for guidelines on measurement-based care and feedback in professional practice. These guidelines include a statement that therapists should regularly assess the treatment process and outcomes and integrate this information into ongoing collaboration with patients [11]. The Joint Commission [12] urged international scientific organizations to increasingly utilize feedback-informed therapy (FIT) and ROM to assess outcomes, inform purposes and goals, and monitor individual progress to guide decisions on care plans, treatment, or individual services. The Roadmap for Mental Health Research in Europe has also supported the use of ROM [13]. Additionally, national policymakers and regulatory bodies in some countries, such as Australia [14], Canada [15], England [16], and Norway [17], have recommended that outcome measurement in treatment becomes mandatory.

More than fifty studies examined the effectiveness of providing therapists with progress feedback [18]. Some meta-analyses that compared the effects of psychotherapy with progress feedback to psychotherapy without feedback found that feedback methods can enhance the effectiveness of therapy by a small to moderate degree (Hedges' $g=0.10$ to 0.28) [4]. However, the effect sizes were more pronounced in Not on Track cases (Cohen's $d=0.33$), suggesting that therapists adapted their treatment strategy with poorly responding patients based on the feedback [19, 20]. Some studies supplemented progress feedback with clinical support tools [21, 22] to provide assessments of the treatment process with Not on Track patients. The clinical support tools (CSTs) included suggestions on how to develop and maintain the therapeutic alliance [2]. When CSTs were added to the feedback intervention, the effect size increased (Cohen's $d=0.49$). There is evidence that alliance ruptures (i.e., breakdowns in the collaborative relationship between patient and therapist) may occur during therapy and should be addressed by therapists to improve outcomes (Cohen's $d=0.62$) [23]. Some studies suggested that providing *process feedback* (i.e., focusing on patient assessment of perceived therapist empathy or working alliance) can further facilitate the therapeutic process across sessions [24, 25]. For example, session-by-session declines in the therapeutic alliance may indicate a rupture in the alliance [26] and can be used to provide feedback to clinicians. Overall, prior research has shown that the feedback with clinical support tools improved the rates of clinically significant change in Not on Track cases [4, 19, 20].

The effect sizes reported in feedback studies range from negligible (<0.20) to large (>0.80) [27], and there is a need to understand when and how feedback can reliably improve treatment outcomes. The meta-analysis by de Jong et al. [4] found several significant moderators of ROM effectiveness, including the type of outcome measure ($g=0.11$ to 0.34), the type of feedback instrument ($g=0.07$ to 0.24), and the country in which the study was conducted ($g=0.11$ to 0.23). Notably, none of the included studies were conducted in Italy.

In the current study, we develop and describe a new feedback strategy within the framework of the OutProFeed-Italy project. We will examine whether feedback is most effective at improving patient outcomes when

clinical support tools are provided, consistent with previous research [4, 19, 20]. However, we will also provide therapists a novel feedback training and clinical support tools for all their patients (not only for Not on Track cases). Qualitative research has shown that ROM data can increase therapists' awareness of how they have affected patients, improve their humility and empathy, increase patients' understanding of themselves, and involve patients more actively in treatment [28].

Prior reviews also found potential barriers to the implementation and effective use of ROM [29]. For example, organizational obstacles can arise in contexts where service policies, culture, or resources do not align with adopting routine outcome measurement. Technological barriers include the lack of modern information technology systems. Digital technologies have recently provided a groundbreaking opportunity for the practice of ROM [30]. Before these technologies, ROM was predominantly paper-based practices that were susceptible to biases [31]. Digital technologies enable real-time collection of patients' data, allowing therapists to evaluate the data before and after the visit, thereby reducing potential patient recall bias [32, 33]. However, the usability and satisfaction with ROM digital platforms remain a challenge. Insufficient knowledge and training remain barriers to implementing progress monitoring [15]. Moreover, patients who used ROM in their treatment reported some concerns about the motives for adopting outcome monitoring, about a narrow symptom focus, and the need for further explanation of how the data will be used in therapy [34, 35].

Although the effectiveness of providing therapists with progress feedback has been assessed in several international studies, no study was conducted in the Italian context. The feasibility of implementing progress monitoring and practice-oriented research [36] in the Italian cultural context remains unknown. The current study aims to fill this research gap by conducting a large-scale naturalistic ROM study to establish the efficacy and generalizability of feedback in routine clinical practice in Italy. Specifically, we aim to advance the literature on ROM by adopting a broader approach that includes measuring therapeutic alliance fluctuations (alongside outcome monitoring) across sessions, and by providing a clinical support system that can closely integrate feedback on the therapeutic alliance and patient progress into clinical practice [37]. The clinical support system encourages therapists to open a meaningful discussion with patients that links patients' scores to the therapy process, thus actively engaging patients in exploring the meaning of their data. Given the importance of the technology used to collect data in ROM, this project places particular emphasis on assessing the usability of the technologies and their impact on individual practice.

Aims and hypotheses

The primary aim of this study is to evaluate the effectiveness of feedback-informed therapy (FIT) delivered through a digital platform in improving patient outcomes and therapeutic processes in routine outpatient psychotherapy. We expect that FIT will increase the therapist's responsiveness [5], which in turn will have an impact on patients' change from session to session [6].

The objectives of the study include:

Primary objectives

(1) Compare the effects of three conditions—Outcome and process monitoring (OPM), outcome and process monitoring plus feedback with clinical support tools (OPM-F), and treatment as usual (TAU)—on symptom reduction at 4 months and 3-month follow-up.
(2) Examine whether FIT training and supervision enhance therapeutic alliance and session-by-session change.

Secondary objective

(3) Assess the usability and acceptability of the ROM digital platform using quantitative and qualitative methods.

Study hypotheses

The primary hypotheses for the study are as follows:

(H1) Patients whose therapists are in the OPM-F condition will show better outcomes in terms of symptom severity from pre-treatment to the 15th session and 3-month follow-up compared to patients in the OPM and TAU conditions. Concurrently, (H2) patients in the OPM condition will exhibit better outcomes in terms of symptom severity reduction from pre-treatment to the 15th session and 3-month follow-up compared to patients in the TAU condition.
(H3) Patients whose therapists are in the OPM-F condition will show greater improvement in overall psychological distress on a session-by-session basis compared to patients in the OPM condition.
(H4) Patients whose therapists are in the OPM-F condition will report a greater improvement in therapeutic alliance over therapy sessions compared to patients in the OPM and TAU conditions.
(H5) Patients with therapists in the OPM condition will demonstrate a greater pre-post improvement in

therapeutic alliance compared to patients in the TAU condition.

Methods

Study design

This is a three-arm, parallel-group, cluster-randomized controlled superiority trial with a Zelen design and an open-label framework. Participant (i.e., patients and therapists) outcomes are assessed longitudinally, and therapists are randomly assigned to one of three conditions before providing consent and without knowledge of the other conditions [37]. Due to the nature of the interventions, neither therapists nor patients can be blinded to treatment allocation.

The therapists involved in the study will be randomized on a 1:1:1 basis using a random number table or computer-generated random numbers. The randomization process will be conducted by an independent statistician who is blinded to the objectives of the study. According to the Zelen design, the therapists will be blinded to the randomization procedure [38] to reduce bias. Allocation concealment will be ensured, as the statistician will not release the randomization code until the therapist has been recruited into the trial.

Participants will be recruited across Italy. The three conditions to which participants are randomized include (1) outcome and process monitoring (OPM), (2) outcome and process monitoring with therapist training, supervision, and feedback (OPM-F), and (3) treatment as usual (TAU). Because this trial uses a Zelen design, baseline demographic and clinical data will be collected after allocation to study condition and after informed consent has been obtained.

The SPIRIT guideline [39] has been used to design this protocol and to lay out Fig. 1. The SPIRIT DIAGRAM is available in Table 1.

Participants

The study includes two samples. The first sample will consist of psychotherapy trainees and/or psychotherapists, who will be recruited by the researchers involved in this study and their collaborators. The inclusion criteria for therapists are (i) having a valid psychotherapy specialization degree recognized by the Italian Ministry of University and Research (MUR) (https://www.miur.it/ElencoSSPWeb/), (ii) currently in practice; and/or (iii) psychotherapy trainees must be at least in their third year of post-graduate training in an MUR-recognized psychotherapy school. In Italy, psychotherapy is predominantly delivered in private outpatient settings rather than within public mental health services. Therefore, the study setting reflects routine real-world clinical practice. There will be no restrictions on the type of psychotherapy used by the recruited professionals, but the treatment must be a psychological therapy for mental health-related issues.

The second sample includes patients who will be recruited and then treated by therapists. Each therapist involved in the project will recruit from 2 to a maximum of 5 patients. We are aiming for an average of 3 patients per therapist. Patient participants will meet the following inclusion criteria: (i) have attended less than 3 sessions with the recruited psychotherapist and (ii) are adults 18 years of age or older. Patients with a diagnosis of psychosis and neurocognitive disorders will be excluded because these conditions may preclude psychotherapeutic work [6].

Procedures

The study will take place at the University of Bergamo in collaboration with the University of Palermo and the Polytechnic University of Milan. The research study strictly adheres to the ethical guidelines outlined by the American Psychological Association (APA) and the principles outlined in the Declaration of Helsinki [40]. The Ethical Committee of the University of Bergamo approved all materials and procedures. Any modifications to the protocol which may impact the conduct of the study will require a formal amendment to the protocol. All participants in the study will provide informed consent. Participation is entirely voluntary. All self-report questionnaires will be completed via a secure web link through the Mindy digital platform, respecting all parameters relating to General Data Protection Regulation (GDPR) privacy regulations. Data are recorded and stored with the agreement between professionals and patients using the Mindy platform and the University of Bergamo. Given the minimal risks of the trial, a formal data monitoring committee was not needed. In terms of auditing, an independent committee of the University of Bergamo will conduct periodic independent review of core trial processes and documents. The Mindy digital platform is described in more detail below.

Data collection schedule

Demographics and questionnaire data will be collected via the Mindy platform after the digital registration process for all therapists and their respective patients. Regarding the main outcome measures, therapists and patients in each study condition complete measures at T0 (at the start of the study therapy sessions), T2 (the 15th session), and T3 (3 months post-treatment which differs for each patient). Regarding the session-by-session outcome and process measures, each study condition varies. In the OPM condition, patients complete outcome measures before each session and process

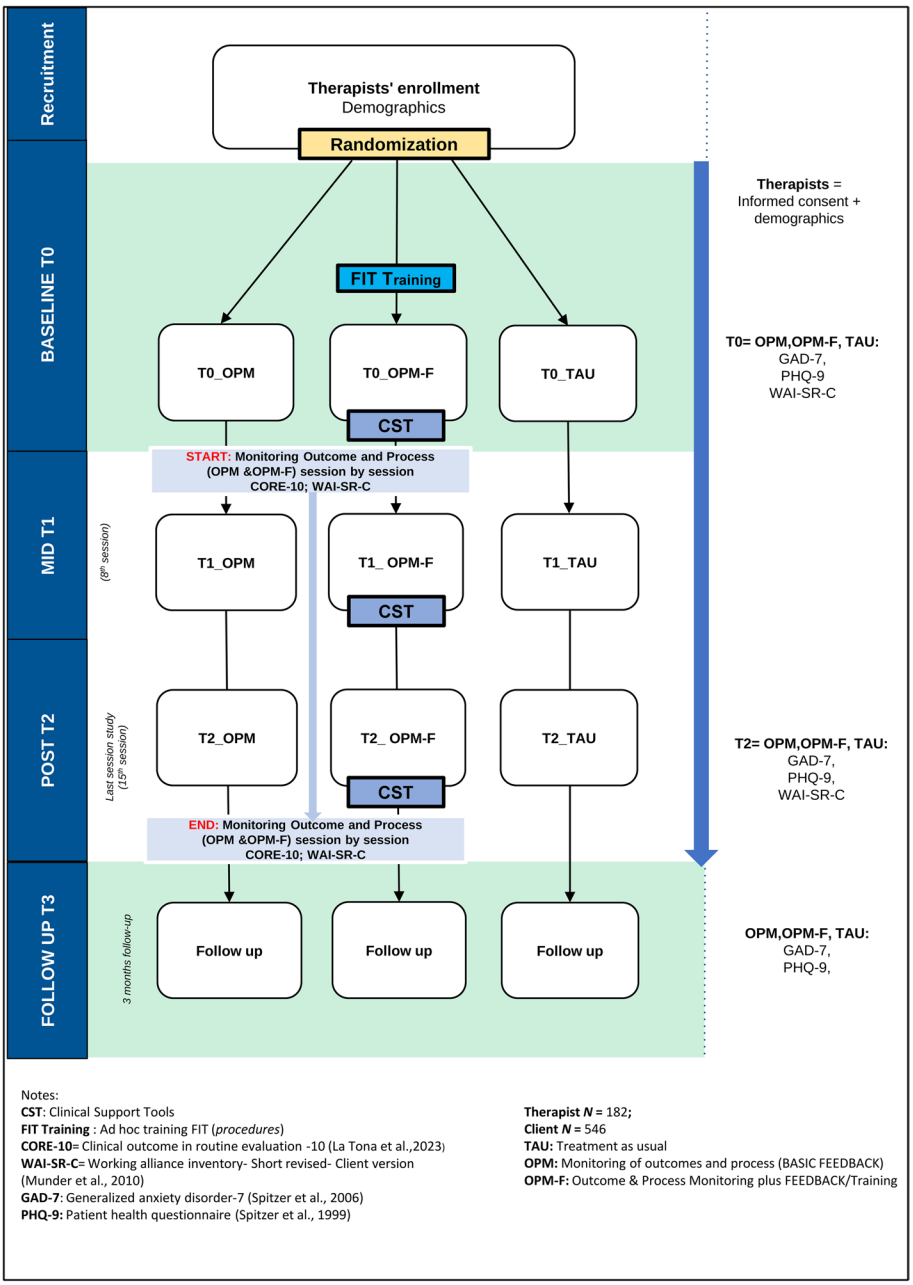

Fig. 1 OutProFeed-Italy study design

measures after each psychotherapy session through the Mindy platform. Therapists in this condition receive only raw scores on these measures and their graphical representations. In the OPM-F condition, patients similarly complete process and outcome measures for each session. Therapists receive training, supervision, and feedback with the clinical support tool on the patient's session-by-session progress and ratings of the therapeutic alliance. In the treatment as usual (TAU) condition, therapists and patients proceed with psychotherapy as they normally would. In this condition, therapists and patients use the Mindy platform to complete outcome measures at T0, T2, and T3 and process measures at T0 and T2 (Fig. 1), but without accessing the data. Under all conditions, no interventions or concomitant care are explicitly prohibited during the trial. To improve adherence among both patients and therapists, the Mindy platform automatically sends a

Table 1 SPIRIT diagram

STUDY PERIOD	ENROLLMENT	BASELINE	MID-POINT	POST	FOLLOW UP
TIMEPOINT	-T0 (Screening)	T0 (Baseline)	T1 (8th session)	T2 (15th session)	(3 months post)
ENROLLMENT					
Therapist Eligibility (screening)	X				
Patient Eligibility (screening)	X				
Informed Consent (Therapists & Patients)		X (pre-baseline)			
Randomization (Zelen design)	X				
INTERVENTIONS					
OPM (Feedback Basic)		X	X	X	
OPM-F (FIT training & CST)		X	X	X	
TAU					
ASSESSMENTS - THERAPISTS					
Baseline data (e.g., demographics)	X				
Supervision (OPM-F only)			X	X	
ASSESSMENTS - PATIENTS					
Baseline data (e.g., demographics)	X				
Outcome measures (GAD-7, PHQ-9)					
OPM		X		X	X
OPM-F		X		X	X
TAU		X		X	X
Progress monitoring (CORE-10)					
OPM (every session)		●	———	●	
OPM-F (every session)		●	———	●	
TAU					
Process monitoring (WAI-SR-C)					
OPM (every session)		●	———	●	
OPM-F (every session)		●	———	●	
TAU (only T0 and T2)		X		X	

CST clinical support tools, *OPM* outcome process monitoring, *OPM-F* outcome process monitoring plus experimental feedback, *TAU* treatment as usual

reminder notification if the questionnaire has not been completed within 24 h of the scheduled appointment.

Therapist training and feedback

Therapists in the OPM-F condition will receive specific training on procedures and techniques related to feedback-informed therapy (FIT) based on information material, explanatory videos, and examples of "what" and "how to manage" NOT (*Not on Track*) patients based on the book "*Routine Outcome Monitoring and Feedback in Psychological Therapies*" [29] suitably translated for the Italian context. During the study's therapy phase (lasting 15 sessions), the clinical support tools (CST) will guide therapists in the OPM-F condition. The CST will help the therapist to engage patients in discussions about ROM and to facilitate dialogue about the reported data.

Short videos were developed and integrated into the CST system that will guide the practitioner in the OPM-F condition step by step to handle *Not on Track* cases as well as *On Track* cases. The scripts were developed by the

research team, and artificial intelligence (AI) was used to generate the voice narration. The system provides clinical case examples, ad hoc questions about the symptom condition, the therapeutic relationship, feedback, and the meaning of routine monitoring of patient progress and therapeutic processes. To address the issue of acceptability and relevance of the procedures, the feedback goes beyond psychological distress and includes the state of the therapeutic alliance and how to repair alliance ruptures should they occur [4, 6].

Additionally, therapists in the OPM-F condition will receive monthly supervision (for 3 months) to provide ongoing clinical support on FIT and ROM, including practical discussion of the most challenging clinical cases and possible therapeutic solutions. The therapists randomized to the OPM and TAU conditions will receive training/supervision on FIT at a later stage after their participation in the study is completed.

Main features of Mindy

The custom digital platform "Mindy", originally developed by software engineers, was adapted for this study through low-cost integrations funded by the project.

Mindy is a digital platform designed to facilitate the work of the therapist. Its main features are a calendar for appointments, document management (e.g., informed consents, session reports, patient management), an integrated questionnaire submission management system with automatic and standardized scoring of copyright-free measures, a dashboard to monitor patient progress (see *"Measures"* for details) and the therapeutic alliance (see *"Measures"* for details), and a system for in-person and online sessions. We will use Mindy for session and patient management, as well as for the computerized administration of instruments.

The platform was customized for this project, with features specific to the study conditions. In the OPM condition, the platform will be used without the CST; therapists receive feedback on patient scores but no assistance. In the OPM-F condition, feedback-informed therapy (FIT) will be integrated, providing therapists with situation alerts (e.g., when a patient is Not on Track, see *"Procedures"* for details) and with innovative clinical support tools (CST) that include videos to aid therapists in managing therapeutic situations based on patient self-report of progress (see *"Procedures"* for details). The clinical support tools (CST) will provide digital alerts indicated on the Mindy dashboard of those patients defined as "*Not on Track*" [29] defined as patients who are not responding well to therapy or are deteriorating in certain aspects (outcomes or therapeutic alliance). Alert notifications will be triggered by questionnaire scores that indicate reliable change from session to session (see *"Measures"* section) [41]. Therapists in the OPM-F condition also receive supervision on the use of the CST. In the TAU condition, Mindy will provide therapists only with simple medical records without any other feedback or assistance.

Therapists involved in the study (across all conditions) will be introduced to the use of the Mindy digital platform (they will receive a user manual) and its features (a user manual with technical specifications will be sent to participants). Therapists will receive specialized training on usage depending on the condition to which they are assigned, as depicted in Fig. 1.

Measures

We will use a demographic questionnaire designed for therapists and patients (including age [in years], sex [male/female], gender identity [male/female/non-binary/other], marital status [single/married/cohabiting/divorced/widowed], and education level [categorized according to the Italian educational system]). Contact information will be collected for administrative purposes only and will not be included in the analyses.

Patient questionnaires

Primary outcomes

The Italian version of the General Anxiety Disorder scale (GAD-7; [42]) is a 7-item self-report screening tool for assessing generalized anxiety disorder (GAD). Each item is rated on a 4-point Likert scale (from 0 = "Not at all" to 3 = "Nearly every day"), with higher scores reflecting greater severity of GAD. Specifically, scores from 0 to 4 indicate minimal anxiety, 5 to 9 mild anxiety, 10 to 14 moderate anxiety, and 15 to 21 severe anxiety. A change of 6 points indicates reliable improvement or deterioration from one assessment to the next.

The Italian version of the Patient Health Questionnaire (PHQ-9; [43]) is a 9-item self-report instrument assessing depression symptoms. Each item is rated on a 4-point Likert scale (from 0 = "Not at all" to 3 = "Nearly every day"), with higher scores indicating greater severity of depression. Scores from 0 to 4 indicate an absence of depressive symptoms, 5 to 9 mild depression, 10 to 14 moderate depression, 15 to 19 moderately severe depression, and 20 to 27 severe depression. A change of 5 points indicates reliable improvement or deterioration from one assessment to the next.

Progress monitoring

The *Italian version of the Clinical Outcomes in Routine Evaluation* (CORE-10; [41, 44]) is a short 10-item measure to explore psychological distress, developed for monitoring outcomes in clinical settings. The CORE-10 is a shortened version of CORE-OM with 34 items.

It comprises three domains: (i) problems: depression (2 items), anxiety (2 items), physical (1 item), and trauma (1 item); (ii) functioning: general functioning (1 item), social functioning (1 item), and close relationships (1 item); and (iii) risk: towards oneself (1 item). Items are rated on a 5-point Likert scale (from 0 = not at all to 4 = most or all the time), and higher total scores (ranging from 0 to 40) indicate greater distress. To enhance the validity of the feedback, the CORE-10 was adopted as an independent measure of patient progress, distinct from measures of pre-post outcomes [6]. Alert notifications will be triggered for therapists in the OPM-F condition by CORE-10 questionnaire scores that significantly worsen by at least 6 points from one session to the next. A 6-point change indicates a reliable change as outlined by Barkham and colleagues [41].

Process monitoring

The adapted version of the Italian translation of theRevised–Clie Working Alliance Inventory-Short Revised-Client Version (WAI-SR-C; [45–47]). The Working Alliance Inventory-Short Revised (WAI-SR-C) is the short version with 12 items [48]. It measures the emotional bond between patient and therapist, and their level of agreement with the tasks and goals of therapy. Each item is rated on a 5-point Likert scale, from 1 (never) to 5 (always). The reliability and validity of WAI-SR-C have been repeatedly supported in a wide range of studies [46, 49].

In the OPM and OPM-F conditions, we will use the WAI-SR-C to identify therapeutic alliance ruptures that may occur from one session to the next. Within the first five sessions, an alliance rupture will be defined by the method described by Stevens et al. [50]. If a patient's WAI-SR-C mean item score drops from one session to the next by 0.26 to 1 point, then this indicates a moderate risk of an alliance rupture, whereas a drop of one point or more for one or more consecutive sessions will trigger an alert for a severe risk of an alliance rupture. A resolution of the rupture will be indicated by a return to within 0.25 points of a pre-rupture WAI-SR-C score. From the sixth to the fifteenth session, the method described by Lipner et al. [51] will be used to identify an alliance rupture. This procedure involves an idiographic approach based on the patient's "moving average" and provides a more reliable estimate of alliance ruptures [52]. In this approach, the patient's average WAI-SR-C score and its standard deviation are updated after each assessment. If the patient's WAI-SR-C score in a particular session is at least 1.5 standard deviations below the mean of their preceding sessions, an alert for a moderate alliance rupture will be triggered. However, if the patient's WAI-SR-C score in a particular session is at least 2 standard deviations below their mean of their preceding sessions, then an alert for a severe alliance rupture will be triggered. A rise in the WAI-SR-C score of at least 1.5 standard deviations of the patient's mean following an alliance rupture will indicate the resolution of the rupture.

Sample size estimation

We performed an a priori sample size estimation with the Optimal Design Plus 3.01 software [52] for a three-level multilevel model in which 4 repeated measurements of the outcomes are nested within patients who, in turn, are nested within therapists. Previous research found a mean effect size of $d = 0.27$ for the effect of ROM on patients' outcomes [53] and an intraclass correlation coefficient (ICC) of 0.011 for therapist effects on outcomes [54]. Hence, with a type I error rate set at 0.05, we require 182 therapists (i.e., 61 per study arm) with an average of 3 patients per therapist (546 patients for the entire study) to achieve power of 0.80.

Data analysis plan

Descriptive statistics will be reported for all study variables. Baseline demographic and clinical characteristics will be summarized by treatment condition using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Outcome measures at each assessment point will be described using means and standard deviations, stratified by study condition.

To test the primary hypotheses, 3-level hierarchical mixed-effects models will be used with repeated measures of psychological distress, symptom severity, or therapeutic alliance values at level 1, nested within all randomized patients at level 2, and therapists at level 3. Study conditions (OPM, OPM-F, TAU) will be coded with indicator variables and modeled at level 3 [55]. We will use full maximum likelihood estimation and allow all parameters to vary. Baseline values will be included as part of the repeated-measures structure within the mixed-effects models rather than as covariates, which allows estimation of treatment-by-time interactions without relying on change scores.

Statistical significance will be set at $\alpha = 0.05$ (two-tailed), and 95% confidence intervals will be reported for all primary effect estimates. All statistical analyses will be conducted using IBM SPSS Statistics (version 30) [56] and HLM software (version 8.2) [57].

Missing data

We will use all available post-treatment and follow-up data from all patients discontinuing treatment when possible. Data analyses will be conducted using the intent-to-treat (ITT) sample, with all participants analyzed according to their original allocation. Due to the

short recruitment period, no interim analyses will be performed.

The impact of missing data will be evaluated using pattern mixing models (PMM). Mixed-effects modeling with maximum likelihood estimation will provide unbiased parameter estimates under the assumption of data missing at random. To assess potential deviations from this assumption, we will examine whether missingness is systematically associated with baseline demographic or clinical characteristics, treatment condition, or early symptom change trajectories. If significant associations are detected, these missing data patterns will be modeled explicitly as recommended by Gallop and Tasca [58].

Discussion

The results of this study will provide valuable insights into the benefits of feedback-informed therapy (FIT) and the utility of the Mindy digital platform in improving mental health outcomes for patients and psychotherapy processes in Italy. We expect that patients whose therapists received training and support in FIT (in the OPM-F condition) will show better symptomatic outcomes, lower dropout rates, and a greater increase in the therapeutic alliance compared to patients in the other two conditions (OPM and TAU). The provision of regular feedback on patient progress and the therapeutic alliance, combined with specific training and ongoing supervision for therapists in the OPM-F condition, is expected to enhance the therapist's ability to tailor treatment and address emerging challenges. Such findings would be consistent with the key principles of FIT, which emphasize the use of real-time data to inform clinical decisions and improve outcomes [20, 59].

The use of clinical support tools (CST) integrated with the monitoring system is another key component of the OutProFeed-Italy project. We expect that, in line with recent studies [29], our CST system, together with explanatory short videos on how to handle difficult situations (i.e., conditions defined as "*Not on Track*"), can make the therapist (trained with specific FIT training) even more effective in improving patients' symptoms and the therapeutic alliance.

Alliance ruptures are common in psychotherapy, and therapists' ability to quickly identify and address them can be crucial for maintaining positive outcomes [23]. FIT systems that incorporate measures of the therapeutic alliance and provide therapists with feedback about alliance fluctuations may help therapists become more attuned to relational dynamics and better equipped to repair ruptures as they arise [26].

In this protocol, we have indicated the main outcomes of the OutProFeed-Italy study. However, we also intend to study the usability of Mindy, which will provide valuable insights into the characteristics that such platforms should have to be used effectively for ROM. Using both qualitative and quantitative methodologies, we will assess both therapists' and patients' perspectives of the platform and identify potential barriers or facilitators to its adoption. These results will be crucial for future practices, as the acceptability of digital tools is fundamental to integrating ROM practices in psychotherapists' work in an unbiased and sustainable way [31, 33].

The limitations of the study will be acknowledged in the study implementation and in the interpretation of its results. First, the self and therapist evaluation of patients may be a time-consuming burden, thus reducing engagement. However, processes built into Mindy, such as clear explanations of the benefits of FIT and ease of using the platform, may increase collaboration and engagement of therapists in the study. We expect that therapist engagement and ease of using the digital platform may also reduce the burden placed on patients to complete outcome and process measures. Second, the evaluations will be done by administering self-report instruments, which could introduce bias in interpreting the results. However, we also intend to collect the therapist's perspective, which might also help account for possible bias. Third, the digital platform may not be accepted by all therapists [29]. To increase uptake, we designed the Mindy digital platform to allow easy management of FIT and ROM and to provide personalized feedback [29]. Fourth, therapists and patients who are assigned to the TAU condition may drop out of the study at a higher rate as sometimes happens in control conditions of RCTs. We will use the Zelen design to reduce demoralization caused by assignment to a control condition (TAU).

The widespread adoption of FIT could have significant public health implications. Research has shown that FIT can improve patient outcomes on average and reduce negative outcomes such as treatment dropout [5, 6]. Given this, implementing FIT could lead to increased well-being and reduced burden on mental health systems [11]. Some health authorities, such as Australia [14], Canada [15], England [16], and Norway [17], have recommended that outcome measurement in treatment be mandatory, recognizing its potential value [12]. As FIT becomes more established, it will be important to consider how to scale up implementation to reach a wider community of therapists and patients. Ensuring equitable access to FIT could help address disparities in mental health care in Italy.

Overall, the results of this study will provide important guidance for future interventions in the Italian healthcare system, promoting a culture of mental health that emphasizes the routine measurement of treatment progress. The findings will provide valuable insights into the

benefits of feedback-informed therapy and the innovative Mindy system, potentially paving the way for wider adoption of these approaches to improve the quality and effectiveness of psychotherapeutic interventions in Italy and beyond [6, 11].

Abbreviations

RCT	Randomized controlled trial
FIT	Feedback-informed therapy
ROM	Routine outcome monitoring
CST	Clinical support tools
TAU	Treatment as usual
OPM	Outcome process monitoring
OPM-F	Outcome process monitoring plus experimental feedback
CORE-10	Clinical Outcomes in Routine Evaluation
GAD-7	General Anxiety Disorder
PHQ-9	Patient Health Questionnaire
GDPR	General Data Protection Regulation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-026-09693-5.

Supplementary Material 1.

Supplementary Material 2.

Trial status

The current protocol is updated on 28 February 2026. Data collection started in November 2024 and will end approximately in March 2026.

Dissemination policy

A structured dissemination strategy is in place, including publication in peer-reviewed scientific journals, presentations at national and international conferences, and the organization of open seminars targeting researchers and academics, mental health professionals, and study participants.

Authors' contributions

The trial sponsor is the University of Bergamo (Italy). AC is the PI of the project: he conceived it and is responsible for its realization. AC, ALT, GLC, CM, AC^2, and GAT designed the study protocol. ALT, AB, MVO, AC^2, and GAT contributed to drafting, revising, and finalizing the manuscript. BP, AC, LP, CM, ALT, and GLC contributed to the scientific discussion by providing essential feedback. AC, ALT, AB, BP, LP, CM, MVO, AC^2, VO, and GAT contributed to editing the final manuscript.

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Data availability

Datasets generated and analyzed during the current study and statistical materials will be available on https://clinicaltrials.gov/study/NCT06356961. The study's pre-registration is available on the ClinicalTrials (NCT06356961).

Declarations

Ethics approval and consent to participate

The research study strictly adheres to the ethical guidelines outlined by the American Psychological Association (APA) and the principles outlined in the Declaration of Helsinki (seventh revision, 2013). The Ethics Committee of the University of Bergamo approved all materials and procedures (prot. n. 0080350). Before participating in the study, all participants will provide informed consent.

Consent for publication

The anonymized dataset is available upon reasonable request for secondary research purposes.

Competing interests

BP received compensation for consulting services and/or speaking activities from Liquidweb S.r.l. She is Associate Editor for *Frontiers in Neuroscience*. All other authors declare that they have no competing interests.

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References

1. Barkham M, Lambert MJ. The efficacy and effectiveness of psychological therapies. In: Bergin and Garfield's handbook of psychotherapy and behavior change: 50th anniversary edition. 7th ed. Hoboken, NJ, US: John Wiley & Sons, Inc.; 2021. p. 135–89.
2. Lambert MJ. Prevention of treatment failure: the use of measuring, monitoring, and feedback in clinical practice. American Psychological Association; 2010.
3. Lutz W, De Jong K, Rubel J. Patient-focused and feedback research in psychotherapy: where are we and where do we want to go? Psychother Res. 2015;25(6):625–32. https://doi.org/10.1080/10503307.2015.1079661.
4. De Jong K, Conijn JM, Gallagher RAV, Reshetnikova AS, Heij M, Lutz MC. Using progress feedback to improve outcomes and reduce drop-out, treatment duration, and deterioration: a multilevel meta-analysis. Clin Psychol Rev. 2021;85:102002. https://doi.org/10.1016/j.cpr.2021.102002.
5. Delgadillo J, McMillan D, Gilbody S, De Jong K, Lucock M, Lutz W, et al. Cost-effectiveness of feedback-informed psychological treatment: evidence from the IAPT-FIT trial. Behav Res Ther. 2021;142:103873. https://doi.org/10.1016/j.brat.2021.103873.
6. Barkham M, De Jong K, Delgadillo J, Lutz W. Routine outcome monitoring (ROM) and feedback: research review and recommendations. Psychother Res. 2023;33(7):841–55. https://doi.org/10.1080/10503307.2023.2181114.
7. Barber J, Resnick SG. Collect, share, act: a transtheoretical clinical model for doing measurement-based care in mental health treatment. Psychol Serv. 2023;20(Suppl 2):150–7. https://doi.org/10.1037/ser0000629.
8. Lambert MJ, Whipple JL, Smart DW, Vermeersch DA, Nielsen SL, Hawkins EJ. The effects of providing therapists with feedback on patient progress during psychotherapy: are outcomes enhanced? Psychother Res. 2001;11(1):49–68. https://doi.org/10.1080/713663852.
9. Persons JB, Koerner K, Eidelman P, Thomas C, Liu H. Increasing psychotherapists' adoption and implementation of the evidence-based practice of progress monitoring. Behav Res Ther. 2016;76:24–31. https://doi.org/10.1016/j.brat.2015.11.004.
10. Wright CV, Goodheart C, Bard D, Bobbitt BL, Butt Z, Lysell K, et al. Promoting measurement-based care and quality measure development: the APA mental and behavioral health registry initiative. Psychol Serv. 2020;17(3):262–70. https://doi.org/10.1037/ser0000347.
11. Boswell JF, Hepner KA, Lysell K, Rothrock NE, Bott N, Childs AW, et al. The need for a measurement-based care professional practice guideline. Psychotherapy. 2023;60(1):1–16. https://doi.org/10.1037/pst0000439.
12. The Joint Commission. 2018. R3.Report: requirement, rationale, reference. Located at: A complimentary publication of The Joint Commission Issue 13.

13. Emmelkamp PMG, David D, Beckers T, Muris P, Cuijpers P, Lutz W, et al. Advancing psychotherapy and evidence-based psychological interventions. Int J Methods Psychiatr Res. 2014;23(S1):58–91. https://doi.org/10.1002/mpr.1411.
14. Burgess P, Pirkis J, Coombs T. Routine outcome measurement in Australia. Int Rev Psychiatry. 2015;27(4):264–75. https://doi.org/10.3109/09540261.2014.977234.
15. Tasca GA, Angus L, Bonli R, Drapeau M, Fitzpatrick M, Hunsley J, et al. Outcome and progress monitoring in psychotherapy: report of a Canadian Psychological Association task force. Can Psychol Psychol Can. 2019;60(3):165–77. https://doi.org/10.1037/cap0000181.
16. Clark DM. Realizing the mass public benefit of evidence-based psychological therapies: the IAPT program. Annu Rev Clin Psychol. 2018;14(1):159–83. https://doi.org/10.1146/annurev-clinpsy-050817-084833.
17. Knapstad M, Nordgreen T, Smith ORF. Prompt mental health care, the Norwegian version of IAPT: clinical outcomes and predictors of change in a multicenter cohort study. BMC Psychiatry. 2018;18(1):260. https://doi.org/10.1186/s12888-018-1838-0.
18. Lutz W, de Jong K, Rubel JA, Delgadillo J. Measuring, predicting, and tracking change in psychotherapy. In: Bergin and Garfield's handbook of psychotherapy and behavior change: 50th anniversary edition. 7th ed. Hoboken, NJ, US: John Wiley & Sons, Inc.; 2021. p. 89–133.
19. Lambert MJ, Whipple JL, Kleinstäuber M. Collecting and delivering progress feedback: a meta-analysis of routine outcome monitoring. Psychotherapy. 2018;55(4):520–37. https://doi.org/10.1037/pst0000167.
20. Shimokawa K, Lambert MJ, Smart DW. Enhancing treatment outcome of patients at risk of treatment failure: meta-analytic and mega-analytic review of a psychotherapy quality assurance system. J Consult Clin Psychol. 2010;78(3):298–311. https://doi.org/10.1037/a0019247.
21. Harmon C, Hawkins EJ, Lambert MJ, Slade K, Whipple JS. Improving outcomes for poorly responding clients: the use of clinical support tools and feedback to clients. J Clin Psychol. 2005;61(2):175–85. https://doi.org/10.1002/jclp.20109.
22. Lutz W, Rubel JA, Schwartz B, Schilling V, Deisenhofer AK. Towards integrating personalized feedback research into clinical practice: development of the Trier Treatment Navigator (TTN). Behav Res Ther. 2019;120:103438. https://doi.org/10.1016/j.brat.2019.103438.
23. Eubanks CF, Muran JC, Safran JD. Alliance rupture repair: a meta-analysis. Psychotherapy. 2018;55(4):508–19. https://doi.org/10.1037/pst0000185.
24. McClintock AS, Perlman MR, McCarrick SM, Anderson T, Himawan L. Enhancing psychotherapy process with common factors feedback: a randomized, clinical trial. J Couns Psychol. 2017;64(3):247–60. https://doi.org/10.1037/cou0000188.
25. Tzur Bitan D, Kivity Y, Ganor O, Biran L, Grossman-Giron A, Bloch Y. The effect of process and outcome feedback in highly distressed outpatients: a randomized controlled trial. Psychother Res. 2020;30(3):325–36. https://doi.org/10.1080/10503307.2019.1627014.
26. Babl A, Rubel J, Gómez Penedo JM, Berger T, Grosse Holtforth M, Eubanks CF. Can session-by-session changes in self-reported alliance scores serve as a measure of ruptures in the therapeutic alliance? J Consult Clin Psychol. 2024;92(2):129–33. https://doi.org/10.1037/ccp0000861.
27. Ferguson CJ. An effect size primer: a guide for clinicians and researchers. Prof Psychol Res Pract. 2009;40(5):532–8. https://doi.org/10.1037/a0015808.
28. Låver J, McAleavey A, Valaker I, Castonguay LG, Moltu C. Therapists' and patients' experiences of using patients' self-reported data in ongoing psychotherapy processes—a systematic review and meta-analysis of qualitative studies. Psychother Res. 2024;34(3):293–310. https://doi.org/10.1080/10503307.2023.2222896.
29. De Jong K, Delgadillo J, Barkham M. Routine outcome monitoring and feedback in psychological therapies. UK: McGraw-Hill Education. 2023.
30. Gual-Montolio P, Martínez-Borba V, Bretón-López JM, Osma J, Suso-Ribera C. How are information and communication technologies supporting routine outcome monitoring and measurement-based care in psychotherapy? A systematic review. Int J Environ Res Public Health. 2020;17(9):3170. https://doi.org/10.3390/ijerph17093170.
31. Suso-Ribera C, Castilla D, Zaragozá I, Ribera-Canudas MV, Botella C, García-Palacios A. Validity, reliability, feasibility, and usefulness of pain monitor: a multidimensional smartphone app for daily monitoring of adults with heterogenous chronic pain. Clin J Pain. 2018;34(10):900–8. https://doi.org/10.1097/AJP.0000000000000618.
32. Hegland PA, Aasprang A, Hjelle Øygard S, Nordberg S, Kolotkin R, Moltu C, et al. A review of systematic reviews on the effects of patient-reported outcome monitoring with clinical feedback systems on health-related quality of life—implications for a novel technology in obesity treatment. Clin Obes. 2018;8(6):452–64. https://doi.org/10.1111/cob.12277.
33. Hallgren KA, Bauer AM, Atkins DC. Digital technology and clinical decision making in depression treatment: current findings and future opportunities: HALLGREN et al. Depress Anxiety. 2017;34(6):494–501. https://doi.org/10.1002/da.22640.
34. Solstad SM, Castonguay LG, Moltu C. Patients' experiences with routine outcome monitoring and clinical feedback systems: a systematic review and synthesis of qualitative empirical literature. Psychother Res. 2019;29(2):157–70. https://doi.org/10.1080/10503307.2017.1326645.
35. Solstad SM, Cooper M, Sundet R, Moltu C. Effects and experiences of idiographic patient-reported outcome measures for feedback in psychotherapy: a systematic review and secondary analysis of the empirical literature. Psychother Res. 2023;1–14. https://doi.org/10.1080/10503307.2023.2283528.
36. Castonguay LG, Atzil-Slonim D, De Jong K, Youn SJ. Practice-oriented research: an introduction to new developments and future directions. Adm Policy Ment Health. 2024;51(3):287–90. https://doi.org/10.1007/s10488-024-01369-z.
37. McAleavey AA, De Jong K, Nissen-Lie HA, Boswell JF, Moltu C, Lutz W. Routine outcome monitoring and clinical feedback in psychotherapy: recent advances and future directions. Adm Policy Ment Health. 2024;51(3):291–305. https://doi.org/10.1007/s10488-024-01351-9.
38. Zelen M. A new design for randomized clinical trials. N Engl J Med. 1979;300(22):1242–5. https://doi.org/10.1056/NEJM197905313002203.
39. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586. https://doi.org/10.1136/bmj.e7586.
40. Krleža-Jerić K, Lemmens T. 7th revision of the declaration of Helsinki: good news for the transparency of clinical trials. Croat Med J. 2009;50(2):105–10. https://doi.org/10.3325/cmj.2009.50.105.
41. Barkham M, Bewick B, Mullin T, Gilbody S, Connell J, Cahill J, et al. The CORE-10: a short measure of psychological distress for routine use in the psychological therapies. Couns Psychother Res. 2013;13(1):3–13. https://doi.org/10.1080/14733145.2012.729069.
42. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092. https://doi.org/10.1001/archinte.166.10.1092.
43. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x.
44. La Tona A, Tagini S, Brugnera A, Poletti B, Aiello EN, Lo Coco G, et al. Italian validation of the Clinical Outcomes in Routine Evaluation 10 (CORE-10): a short measure for routine outcome monitoring in clinical practice. Res Psychother Psychopathol Process Outcome. 2023. https://doi.org/10.4081/ripppo.2023.671.
45. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the working alliance inventory. Psychother Res. 2006;16(1):12–25. https://doi.org/10.1080/10503300500352500.
46. Munder T, Wilmers F, Leonhart R, Linster HW, Barth J. Working alliance inventory-short revised (WAI-SR): psychometric properties in outpatients and inpatients. Clin Psychol Psychother. 2010;17(3):231–9. https://doi.org/10.1002/cpp.658.
47. Paap D, Dijkstra PU. Working Alliance Inventory-Short Form Revised. J Physiother. 2017;63(2):118. https://doi.org/10.1016/j.jphys.2017.01.001.
48. Tracey TJ, Kokotovic AM. Factor structure of the working alliance inventory. Psychological Assessment: A Journal of Consulting and Clinical Psychology. 1989;1(3):207–10. https://doi.org/10.1037/1040-3590.1.3.207.
49. Buono N, Sassier B, Thulesius H, Hoffman R, Nabbe P, Petek D, et al. Translation of the working alliance inventory short revised into Italian using a Delphi procedure and a forward-backward translation. Front Med. 2024;10:1236273. https://doi.org/10.3389/fmed.2023.1236273.
50. Stevens CL, Muran JC, Safran JD, Gorman BS, Winston A. Levels and patterns of the therapeutic alliance in brief psychotherapy. Am J Psychother. 2007;61(2):109–29. https://doi.org/10.1176/appi.psychotherapy.2007.61.2.109.

51. Lipner LM, Muran JC, Eubanks CF, Gorman BS, Winston A. Operationalizing alliance rupture–repair events using control chart methods. Clin Psychol Psychother. 2022;29(1):339–50. https://doi.org/10.1002/cpp.2606.
52. Spybrook J, Raudenbush SW. Optimal design for longitudinal and multilevel research: documentation for the "Optimal Design" software. 2006.
53. Rognstad K, Wentzel-Larsen T, Neumer SP, Kjøbli J. A systematic review and meta-analysis of measurement feedback systems in treatment for common mental health disorders. Adm Policy Ment Health Ment Health Serv Res. 2023;50(2):269–82. https://doi.org/10.1007/s10488-022-01236-9.
54. Delgadillo J, Deisenhofer AK, Probst T, Shimokawa K, Lambert MJ, Kleinstäuber M. Progress feedback narrows the gap between more and less effective therapists: a therapist effects meta-analysis of clinical trials. J Consult Clin Psychol. 2022;90(7):559–67. https://doi.org/10.1037/ccp0000747.
55. Tasca GA, Illing V, Joyce AS, Ogrodniczuk JS. Three-level multilevel growth models for nested change data: a guide for group treatment researchers. Psychother Res. 2009;19:453–61. https://doi.org/10.1080/10503300902933188.
56. IBM Corp. IBM SPSS Statistics for Windows, version 30.0. Armonk, NY: IBM Corp; 2023.
57. Raudenbush SW, Bryk AS, Congdon R, du Toit M. HLM 8: hierarchical linear and nonlinear modeling. Lincolnwood, IL: Scientific Software International; 2019.
58. Gallop R, Tasca GA. Multilevel modeling of longitudinal data for psychotherapy researchers: II. The complexities. Psychother Res. 2009;19:438–52. https://doi.org/10.1080/10503300902849475.
59. Goldberg SB, Rousmaniere T, Miller SD, Whipple J, Nielsen SL, Hoyt WT, et al. Do psychotherapists improve with time and experience? A longitudinal analysis of outcomes in a clinical setting. J Couns Psychol. 2016;63(1):1–11. https://doi.org/10.1037/cou0000131.

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