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Fostering practice-based evidence through routine outcome monitoring in a university psychotherapy service for common mental health problems: a protocol for a naturalistic, observational study

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ABSTRACT

Introduction Data-informed psychotherapy and routine outcome monitoring are growing as referents in psychotherapy research and practice. In Ecuador, standardised web-based routine outcome monitoring systems have not been used yet, precluding data-driven clinical decisions and service management. Hence, this project aims at fostering and disseminating practice-based evidence in psychotherapy in Ecuador by implementing a web-based routine outcome monitoring system in a university psychotherapy service.

Methods and analyses This is a protocol for an observational naturalistic longitudinal study. Progress and outcomes of treatment in the Centro de Psicología Aplicada of the Universidad de Las Américas in Quito, Ecuador will be examined. Participants will be adolescents and adults (≥11 years) seeking treatment, as well as therapists and trainees working at the centre between October 2022 and September 2025. Clients' progress will be monitored by a range of key variables: psychological distress, ambivalence to change, family functioning, therapeutic alliance and life satisfaction. Sociodemographic information and satisfaction with treatment data will be collected before and at the end of treatment, respectively. Also, semi-structured interviews to explore therapists' and trainees' perceptions, expectations and experiences will be conducted. We will analyse first contact data, psychometrics of the measures, reliable and clinically significant change, outcome predictors as well as trajectories of changes. Moreover, we will conduct a framework analysis for the interviews.

Ethics and dissemination The protocol for this study was approved by the Human Research Ethics Committee of the Pontificia Universidad Católica del Ecuador (#PV-10–2022). The results will be disseminated in peer-reviewed scientific articles, at conferences and in workshops.

Trial registration number NCT05343741.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This project targets adults and adolescents, allowing for intragroup and intergroup comparisons of trajectories of change and outcomes.
⇒ Links between changes in psychological distress and three transdiagnostic variables: therapeutic alliance, family functioning and ambivalence to change will be explored.
⇒ Data loss will be prevented by constant supervision of data collection procedures.
⇒ Though causal inferences are not possible from observational studies, ecological validity and generalisability will be strong.
⇒ This is a protocol for a study that will be conducted at a single service with a limited number of therapists; however, it offers a template for other interested services.

INTRODUCTION

Certain characteristics of randomised controlled trials (RCTs) conducted from the evidence-based practice paradigm, such as strict inclusion criteria and control conditions, limit external validity of the findings. To counteract some of these limitations the practice-based evidence (PBE) paradigm has emerged.[1]

PBE studies share, at least, three common features: (1) data come from clinical non-controlled routine practice with inclusion criteria that are minimally restrictive and no researcher-imposed exclusion criteria; (2) the assessed variables should capture routine practice and (3) the research plan and its implementation are not defined by the researcher hierarchically, rather it is devised by close collaboration with clinicians.[2 3] Routine Outcome Monitoring (ROM) is one key approach within PBE. ROM is the common use of measures to explore changes and outcomes during and ideally after treatment in everyday practice. ROM can be

used at different levels (within and/or between clients; intraservice or multiservice) and with different purposes such as, monitoring change, service management, clinical decision-making, feedback for therapists, clients or both, etc.[4] When using ROM, global outcome measures are typically used rather than disorder-specific measures, because they allow assessment of treatment outcomes from a transdiagnostic and transtheoretical perspective and across as many clients as possible.[5–7] However, if a clinic provides highly specialised therapy services (eg, for eating disorders), disorder-specific measures may also be used.[8]

Previous PBE and psychotherapy research studies have been conducted mainly in Europe and North America. Available literature has addressed some core issues in psychotherapy such as effectiveness, therapist effects, therapeutic alliance, participants' characteristics, contextual factors, among others that contribute to change in routine clinical practice.[2] In this protocol, based on the literature review and in collaboration with practitioners, we have included several clinically relevant client variables to assess treatment progress and outcomes. Furthermore, we will explore therapists' effects on outcomes since they have been observed in previous studies.[9–14]

Regarding clients' variables, we will be monitoring outcomes by measuring psychological distress with a set of global outcome measures with two different age groups. Findings in previous studies are mixed: some studies suggest that greater initial symptom severity correlates with lower rates of reliable change, while others state that clients with high distress levels at baseline show greater change.[15–18] There is also diversity of findings about age in studies with adult clients: some have found older adult clients show lower levels of improvement,[19] while others have found the reverse.[20] Broadening the age coverage, Cuijpers *et al*[21] compared the impact of psychotherapies in different life stages and found that children and adolescents showed, on average, significantly lower effect sizes than young adults and middle-aged adults.

Another focus will be on monitoring therapeutic alliance and family functioning, since they are key factors affecting change. Regarding therapeutic alliance, many studies have pointed toward therapeutic alliance and clients' improvement influencing each other on a continuous loop throughout therapy.[19 22–27] Concerning family functioning in adults, previous findings suggest that worse interpersonal functioning in general is related to worse outcomes.[28] Regarding family functioning in adolescents Sawyer and Borduin[29] showed that improvements in family functioning mediated symptom reductions.

Besides those well-studied variables, we will study ambivalence to change given its clinical relevance and under-researched status in PBE studies.[30 31] Ambivalence to change is a significant variable influencing outcomes in both improvement and deterioration cases.[32]

Only a handful of psychotherapy research studies have been conducted in Latin America (LA). Paz *et al*[33] conducted the first review in LA to identify all published articles regarding psychotherapy outcome and change measures and found 207. When conducting their searches, they found 53 096 papers but only 3834 from LA: 7%. Globally, the first paper was published in 1947 but the first from LA was not published until 1990. Their results underline the shortage of research on outcome measures in LA and they showed that there was a particular deficit of LA papers using global rather than diagnosis specific outcome measures. However, their review showed that PBE is an emerging topic in LA.

In Ecuador, only two PBE studies have been published; Zúñiga-Salazar *et al*[34] assessed changes in the psychological distress of LGBTIQA+ people who attended affirmative psychological services and Valdiviezo-Oña *et al*[35] explored the psychological distress outcomes of clients who completed the Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) at least twice at the Centro de Psicología Aplicada (Centre for Applied Psychology, CPA) between 2018 and 2020. To date, no study in Ecuador has assessed ambivalence to change in psychotherapy for any age group and none has explored adolescents' life satisfaction and change in therapy. Finally, no previous study has implemented a web-based ROM system in psychotherapy services in Ecuador.

STUDY OBJECTIVES

General objective

To foster and disseminate PBE in psychotherapy in Ecuador by implementing a pathfinder web-based ROM system in a university psychotherapy service.

Specific objectives

1. To implement a standardised ROM system in a university psychotherapy service in Ecuador.
2. To describe the trajectories of change of clients attending the service.
3. To explore the predictors of change (e.g., sociodemographics, therapeutic alliance, family functioning and ambivalence to change) of clients attending the service.
4. To delve into therapists' perceptions and expectations regarding the implementation of the ROM system in the service.
5. To describe the main challenges and opportunities of implementing a ROM system in psychotherapeutic practice in a university psychotherapy service in Ecuador.

METHODS AND ANALYSIS

Study design

This is a non-experimental, longitudinal, exploratory and descriptive mixed methods study, with a mainly quantitative focus. This study will be conducted in a naturalistic setting, at the CPA of the Universidad de Las Américas (UDLA) in Quito, Ecuador.

Participants

Clients

This is a study of routine practice including both adolescent (11–17 years old) and adult clients, and it adopts the inclusion and exclusion criteria of the centre where it is conducted. All clients who approach the service until September 2025 seeking psychotherapy and are 11 years old or older will be eligible for participation. The CPA offers psychological services for a wide variety of psychological problems; however, severe mental health problems such as psychosis, substance abuse, physical and sexual violence are not admitted for treatment in the centre. Most clients attend one session per week, but some attend two sessions weekly, and others attend a session every 2 weeks. Duration of the therapies varies, ranging from 1 to 20 sessions with a median number of 5 and a mean of 6.52 (*SD* = 4.77; for more details see Valdiviezo-Oña *et al*[35]). Considering the actual client flow (approximately 350 per year), taking into account possible refusals (5%–10%), we expect to collect information from at least 300 adults and 40 adolescents. Based on a meta-analysis,[36] including more than 83 000 adult psychotherapy clients from 669 studies that concludes that almost 20% of clients opt out of psychotherapy, we expect our rate to be alike or lower.

Psychotherapists, trainees and supervisors

This centre employs a co-therapy model, whereby a professional psychotherapist and a clinical psychology trainee work together from different psychotherapeutic models (e.g., cognitive-behavioural, systemic and integrative; for more details, see Valdiviezo-Oña *et al*[35]). There is also a team of supervisors monitoring the progress of all cases. All therapists, trainees and supervisors will be invited to participate. We estimate that we will include around 40–60 psychotherapists and trainees.

Measures

All measures will be offered to the participants in Spanish. Spanish is the official language and the most widely used by the country's inhabitants (93%)[37] with a 94% literacy rate.[38]

Primary outcome measures

Clinical Outcomes in Routine Evaluation System measures

Clinical Outcomes in Routine Evaluation-Outcome Measure

The Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM)[39] is a 34-item self-report instrument designed to be used in heterogeneous services, based on a pan-theoretic core of psychological distress in adults, including: well-being, problems, risk and functioning. Items are scored on a scale from 0 (never) to 4 (always or almost always). Higher scores indicate greater psychological distress. The Spanish version of this measure was translated by Feixas *et al*[40] and has shown good psychometric properties in Spain[41] and Ecuador.[42]

Clinical Outcomes in Routine Evaluation-10

The Clinical Outcomes in Routine Evaluation-10 (CORE-10)[43] is a short psychological distress assessment measure for adults, whose items were drawn from the CORE-OM. It has shown good psychometric properties in its original version in the UK[43] and in its Spanish version in Ecuador, showing a good internal consistency score as well as convergent and discriminant validity (Valdiviezo-Oña *et al.*, submitted for publication).

Young Person's-Clinical Outcomes in Routine Evaluation

The Young Person's-Clinical Outcomes in Routine Evaluation (YP-CORE) is a brief self-report instrument that assesses psychological distress in adolescents.[44] It has 10 items, which are answered on a 5-point scale (0–4). The YP-CORE was translated to Spanish by Feixas *et al*[45] and showed adequate psychometric properties. In the present study, we will use a version of this measure adapted for Ecuador and LA approved by the CORE System Trust (CST; https://www.coresystemtrust.org.uk/), whose psychometric properties are being explored.

Secondary measures

Systemic Clinical Outcome and Routine Evaluation-15

This is a 15-item questionnaire with a scale of 1 to 5, where one means *strongly disagree* and five means *strongly agree*. It was designed to be completed by family members, aged 12 years or older.[46] It has three dimensions: *Strengths*, *Difficulties*, and *Communication*. Lower scores correspond to better family functioning. In addition, the Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15) has two scales ranging from 1 to 10 where participants rate perceived effectiveness of the intervention and perceived severity of the difficulty leading to treatment. The Spanish version of this measure has shown adequate reliability and validity in Spain.[47] This measure will be administered to all clients individually. In couples and family therapy, every attending member will be asked to complete it.

Life Satisfaction Scale

Participants are asked to rate their overall degree of satisfaction with life in the present with the following question: Considerando todos los aspectos, ¿qué grado de satisfacción tiene con su vida? [All aspects considered, how satisfied are you with your life?]. This measure is rated on a 10-point Likert scale, in which 1 represents Nada satisfecho (not at all satisfied) and 10 represents Totalmente satisfecho (totally satisfied). This single item has shown an acceptable reliability, and it is theoretically consistent.[48] This measure will be administered to all clients.

Ambivalence in Psychotherapy Questionnaire

It is a 9-item questionnaire that measures the clients' level of ambivalence toward change in psychotherapy. It includes two subscales, demoralisation and wavering, and an overall score of ambivalence toward change.[30] Both the original version[30] and the Spanish version (Montesano *et*

al., submitted for publication) have demonstrated good psychometric properties, including good convergent and divergent validity.

Therapeutic Alliance Scale

It is a one-item measure created ad hoc for this study that evaluates therapeutic alliance on a 10-point scale, in which 1 indicates: En general, no me siento conectado/a con mi terapeuta, no hemos hablado sobre lo que me interesaba trabajar [In general, I don't feel connected with my therapist, we haven't talked about what I was interested in working on], while 10 indicates: En general, me siento conectado/a con mi terapeuta, hemos hablado sobre lo que me interesaba trabajar [In general, I feel connected with my therapist, we have talked about what I was interested in working on].

Consumer Reports Effectiveness Scale

The Consumer Reports Effectiveness Scale (CRES-4) has four items: one question on satisfaction, one on the level of resolution of the main problem, one on the emotional state before the start of treatment and one question on the emotional state when completing the questionnaire.[49] These questions allow interpretations to be made about clients' perceived change in their emotional state, satisfaction and resolution of the problem.

Instruments for collecting sociodemographic and clinical information

CORE Therapy Assessment Form

The CORE Therapy Assessment Form (CORE-A-TAF) is a pragmatic form designed to be filled out by therapists at baseline. The CORE-A-TAF includes referral information, sociodemographic data on the client and data on the nature, severity and duration of the client's problems.[50 51] The CORE-A-TAF includes questions regarding risk which can be later contrasted with the clients' self-reported data in the CORE-OM, CORE-10 and YP-CORE items that measure risk. We will use the Spanish version of this measure, which has already been translated for its use in Ecuador and approved by the CST.

CORE End of Therapy

The CORE end of therapy (CORE-A-EoT) is a pragmatic form designed to be filled out by therapists immediately after treatment completion. The CORE-A-EoT reports information regarding the treatment, including the number of sessions, type of therapy, length and frequency of sessions, whether the ending was planned or unplanned, and the potential benefits of therapy.[50 51] We will use its Spanish version, which has already been translated for its use in Ecuador and approved by the CST.

Qualitative techniques

Semi-structured interview

Semi-structured interviews will be conducted with the centre's therapists, trainees and supervisors using some predefined but open-ended questions.[52] The interview questions (see online supplemental material S1 for the interview guides in the original Spanish version and their translation into English) are related to this study's fourth specific objective; therefore, they will address topics such as: knowledge and expectations regarding ROM, perception of therapists' and trainees' agency, as well as perception of usability, risks and benefits of ROM, overall experience and perception of the implementation of the ROM system in the service. All interviews will be recorded and stored securely until this study is completed in an institutional account's shared online folder with two-step verification. Only the principal investigator (JV-O) and research assistants will have access to this folder.

Procedure

The centre has already approved the implementation of the project, data collection started in October 2022 and is planned to end in September 2025. All adolescent and adult clients initiating psychotherapy at the CPA will be invited to participate. Once enrolled, the clients will be asked to complete the measures throughout the therapeutic process. Figure 1 shows an example of the assessment timeline for both an adult and an adolescent client. For clients' data collection, we will use MarBar, a free online software available at https://www.marbarsystem.com/ for Spanish-speaking therapists and centres.

In addition, individual semi-structured interviews will be conducted with psychotherapists and new trainees at the beginning and at the end of each term with each new cohort of trainees. The first will address expectations and perceptions regarding ROM, whereas the latter will address general experiences and perceptions regarding the implementation of the ROM system.

Data analysis

The units of analysis will be clients and psychotherapists undergoing and providing therapy at the CPA, respectively. In this section, we will briefly describe how data will be analysed. For further details, please refer to online supplemental table S2. Here we present the preplanned analyses; however, post-hoc analyses may arise. We will clearly state post-hoc findings as such in future publications.

Quantitative analyses

The analyses in this project are framed in the Problem, Plan, Data, Analysis, Conclusions and Communication approach.[53 54] The problem is to study clients' progress and outcomes of treatment regarding psychological distress, life satisfaction, ambivalence in psychotherapy, family functioning and therapeutic alliance in a university psychotherapy service in Ecuador. When addressing this problem, the first specific objective is accomplished. The plan is to analyse the routinely collected item-level data from the aforementioned measures.

All quantitative analyses will be performed with R in Rstudio[55 56] and they will contribute to accomplishing the second and third specific objectives: to describe the trajectories of change of clients attending the service

	Before enrollment	Treatment										Termination
TIMEPOINT	0	W_1	W_2	W_3	W_4	W_5	W_6	W_7	W_8	W_9	W_x	
FIRST CONTACT WITH CPA												
Informed consent	x											
ADULTS' ASSESSMENTS												
CORE-A-TAF		X										
CORE-OM, LSS		X										X
CORE-10			X	X	X	X	X	X	X	X	X	
SCORE-15		X			X							X
APQ		X			X				X			
TAS		X	X	X	X	X	X	X	X	X	X	X
CRES-4												X
CORE-A-EoT												X
ADOLESCENTS' ASSESSMENTS												
CORE-A-TAF		X										
YP-CORE		X	X	X	X	X	X	X	X	X	X	X
SCORE-15		X			X							X
LSS		X										X
TAS		X	X	X	X	X	X	X	X	X	X	X
CRES-4												X
CORE-A-EoT												X

Figure 1 Example of assessment schedule for clients attending nine sessions. APQ, Ambivalence in Psychotherapy Questionnaire; CORE-A-EOT, CORE End of Therapy; CORE-A-TAF, CORE Therapy Assessment Form; CORE-OM, Clinical Outcomes in Routine Evaluation-Outcome Measure; CORE-10, Clinical Outcomes in Routine Evaluation-10; CRES-4, Consumer Reports Effectiveness Scale; LSS, Life Satisfaction Scale; SCORE-15, Systemic Clinical Outcome and Routine Evaluation-15; TAS, Therapeutic Alliance Scale; YP-CORE, Young Person's-Clinical Outcomes in Routine Evaluation. Note. The CORE-OM and LSS are completed before the first session and after the last session. The CORE-10, SCORE-15, APQ and YP-CORE are completed before the specified sessions. The CORE-A-TAF is completed by the therapists between the initial session and the third session. The TAS after each session. CRES-4 and CORE-A-EoT after the last available session. This flowchart represents an example of the assessment structure for patients who attend at least nine sessions. From that point onwards CORE-10, YP-CORE and TAS data continue to be collected routinely every session. APQ is administered to adult patients every four sessions (W1, W4, W8, etc.) until treatment completion.

and to explore the predictors of change (e.g., sociodemographics, therapeutic alliance, family functioning nd ambivalence to change) of clients attending the service.

First contact analyses

Descriptive statistics of the sociodemographic and clinical characteristics of the participants, as well as of the scores of the measures will be reported. In all analyses, whenever possible, we will report the information with 95% bootstrapped CIs. Additionally, we will evaluate the acceptability and the internal consistency of the CORE-OM, YP-CORE, CORE-10, SCORE-15 and Ambivalence in Psychotherapy Questionnaire (APQ). Correlations between questionnaires will also be explored.

We will evaluate the associations among gender, age and education and the total scores in the first completion of the measures.

Trajectories and predictors of change

Analyses of the trajectories of change in the measures—CORE-10, YP-CORE, APQ and SCORE-15—that are completed on three or more occasions will be performed, at the individual and group level using trajectory plots with two axes (ie, Cat's cradle plots for individual and group

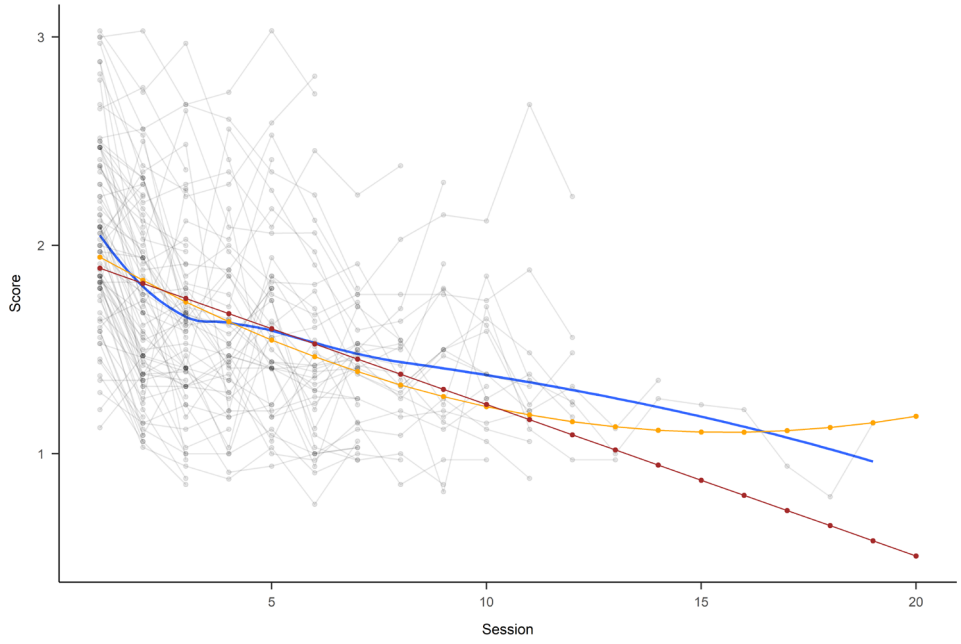

Figure 2 Cat's cradle plot example. Note. This cat's cradle plot example has been created with the data published in the Zúñiga-Salazar *et al*[34] study, however this figure was not included in that article. Besides trajectories of change, this plot shows a nonlinear fit (LOESS regression) — ignoring nesting within patients— in blue, a linear fit in brown and a quadratic fit in orange.

data and Violin plots for group data, see figures 2 and 3). One axis representing the scores on the measure, and the second representing the different assessment points in time. Group trajectories of change will be plotted with violin plots, showing mean scores with 95% CI for each occasion the measures were completed. Predictor/subgroup analyses will be conducted addressing gender, educational level, age and risk levels.

Intrapersonal, intragroup and intergroup differences

This study will have several analytical levels that will produce nested data. To model the dependencies between these levels, this study will use multilevel analyses, and intends to use growth-mixture models (GMM) and latent class growth analyses (LCGA). Multilevel analyses (see the levels of the data in figure 4) will allow to evaluate differences at the individual client level, and at the therapist

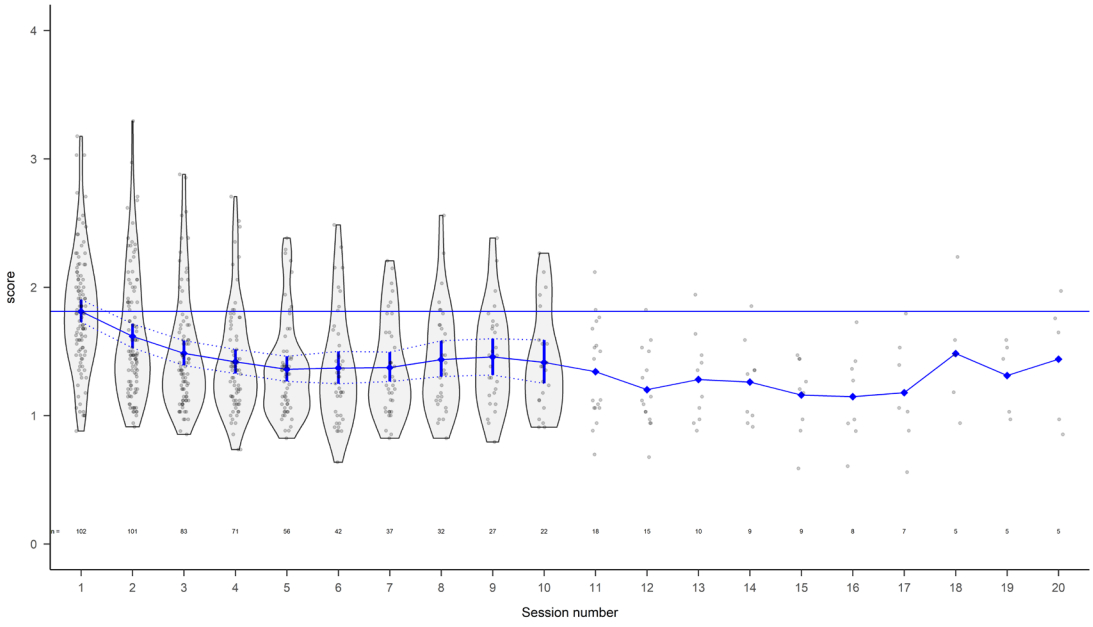

Figure 3 Violin plot example. Note. This Violin plot example summarizes the distributions of scores and means for participants across sessions. The horizontal blue line is the mean score at the first completion. The blue line with interconnected dots shows the mean scores with confidence intervals across sessions.

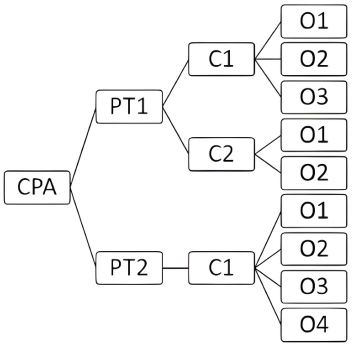

Figure 4 Example of data nesting levels showing two psychotherapists and three participants. PT = Psychotherapist; C = Client; O = Occasions each patient filled out each questionnaire.

level both intragroup (clients of the same therapist) and intergroup (comparing clients from different therapists). In light of the intended nested analyses, to get a power level of 0.80 and assuming five measurements per each participant, we would need to have at least 22 different therapists with at least eight clients each (a minimum recruitment goal of 176 clients).[57]

Successful implementation of GMM and LCGA requires a sufficiently large sample size (at least 300 clients to get acceptable results).[58] The decision to proceed with these analyses will be contingent on sample size but also on the data completeness (missing scores), number of time points, high within-group initial score variability and any marked violation of distributional assumptions. We will consider these criteria on the basis of: (1) a small sample size (<250) limits class identification and can generate model convergence problems[59 60]; (2) at least 200 participants are needed with complete or not more than 20% missing data, high class separation and few classes[61]; (3) few time points (<4) can reduce class enumeration performance and generate bias when estimating random effect variances and covariances[62]; (4) high within-group initial score variability in individuals with similar growth patterns can result in not identifying or differentiating classes with precision[63] and (5) breaking distributional assumptions such as within-class normality in GMM can lead to detecting more groups within the data than there actually are.[64]

Reliable and Clinically Significant Change and Reliable Trend Index

In addition to these group aggregate analyses, we will assess pre–post clinically significant change in the CORE-10, YP-CORE, APQ and SCORE-15 scores using Jacobson and Truax's[65] Reliable Change Index and the Reliable Trend Index to assess change across several time points.[66]

Handling missing data

To handle missing item-level data, we will use prorating whenever possible. Prorating is a technique that takes the mean of the item-level scores at disposal from each individual and imputes the scale scores for each individual if a cut-off criterion—which varies among measures, but usually goes from 50% to 80% complete items—is met. Using this technique only the incomplete cases with fewer missing items than the cut-off criterion will be used for the analyses.[67 68] To minimise the impact of clients opting out of therapy leading to incomplete data we are collecting data for all measures at multiple time points, and specifically for primary outcomes measures, we are collecting data session by session to ensure we always have information on psychological distress from the last available session for each client.

Benchmarking

Benchmarking refers to 'the establishment of reference points to aid the interpretation of data' (p 358).[69] Benchmarking of the following aspects related to the CORE measures will be performed to contrast local data with that from other countries and regions regarding outcomes; baseline score; problems/concerns identified; outcome measure completion rates (acceptability, valid and invalid/partially completed questionnaires); number of sessions; percentage of planned and unplanned treatment ends; attended and unattended sessions and rates of reliable and clinically significant change.

Qualitative analyses

The semi-structured interviews will be analysed using framework analysis. This method was originally developed for use in large-scale policy research, as it permits identifying commonalities and differences in data before focusing on the relationships between different parts of the data.[70] The framework analysis of the interviews will contribute to accomplishing the study's fourth and fifth specific objectives.

DISCUSSION

In Ecuador and in LA, ROM has historically not been a common practice in psychotherapeutic contexts.[33] This project is the first to propose the use of a web-based ROM system assessing several transdiagnostic variables in Ecuador and one of the few ROM systems existing in LA.[71–73]

We have designed this protocol considering many characteristics of high-quality practice-oriented studies, defined by Castonguay *et al*,[2] which include factors related to (1) clinical helpfulness; (2) feasibility and (3) methodological and statistical sophistication. For more details on how these characteristics are addressed in this project, please refer to table 1.

The relevance of the study resulting from this protocol can be discussed considering its short-term, medium-term and long-term benefits as well as considering specific benefits for the university psychotherapy service and benefits for psychotherapy research and practice in Ecuador and LA.

With respect to the benefits for the clinic, in the short-term therapists will be trained and will learn about PBE and ROM in psychotherapy and its potential uses and advantages. In the medium term, the results of this project could contribute to the development of a positive

Table 1 Characteristics of high-quality practice-oriented studies defined by Castonguay *et al*[2] present in this protocol

Criteria	Characteristics present in this protocol
Clinical helpfulness	The study derived from this protocol will provide evidence for improving: the impact of therapy (e.g., outcome, retention and reduction of deterioration); assessment and case formulation; implementation of interventions; as well as monitoring the therapeutic relationship. It will also provide evidence to better understand: the process of therapy, as well as client and therapist characteristics; finally, it will allow to make research serve therapists' needs, considering their experiences with the ROM system.
Feasibility	The study derived from this protocol does not impose drastic changes in everyday practice; the research tasks are easily integrated, and they will be preserved as part of routine clinical practice, from the implementation of the study onwards, even when this project is finished.
Methodological and statistical sophistication	The study derived from this protocol involves repeated assessment of key variables; considers the nesting of the data at multiple levels (repeated measures, clients, therapists); uses within and between clients analyses; uses between therapists analyses; investigates predictor variables and assesses changes and their effect sizes.

feedback loop between practice, training and research at the CPA. For instance, new information about change trajectories leading to changes in clinical practice and additional data collection following the implementation of changes. This knowledge can also be transferred to the syllabi of UDLA clinical psychology undergraduate and postgraduate programmes.

In the long term, this project aims to contribute to establishing outcome monitoring as a routine practice to improve the quality of psychological interventions in individual, couple and family therapy from an integrative data-informed perspective at the CPA. Eventually, clients will benefit the most by receiving a treatment that is in a constant process of refinement.

Regarding benefits for psychotherapy research and practice in Ecuador and LA that transcend this specific centre, in the short term, a culturally contextualised data collection system will be developed, implemented and made available for free to Spanish-speaking clinicians and researchers. This, in the medium term and long term, will allow sharing an open access common strategy for data collection and collaboration toward a global data sharing frame in LA and beyond. It is expected that the standardisation of ROM will yield solid culturally sensitive evidence for patterns in trajectories of change and predictors, serving as a reference for practitioners and researchers alike at the national and regional levels.

In sum, the study derived from this protocol seeks to promote the consistent and widespread use of ROM measures, which could help not only in establishing a culture of PBE in Ecuador and in LA, but also in the creation of practice-based research networks in the field of psychological interventions. These networks are much needed to boost researchers and clinicians' collaboration and sharing of goals, methods and language.[74] The results of this project will constitute a critical first step toward the creation of a big database and the subsequent training of culturally sensitive algorithms to possibly develop normative trajectories of change and expected recovery curves. This kind of advancements has proven to be of great support for psychotherapy practice optimisation, as it allows to enhance treatment outcomes for clients at risk of treatment failure.[75 76]

Given the non-experimental nature of the study proposed in this protocol, its main limitation is related to the difficulty of proving causality, which contrasts with RCTs. In other words, when conducting non-experimental studies, causal relationships cannot strictly be attributed, notwithstanding this type of study can help identify associations between variables as well as relevant areas for psychotherapeutic and research exploration and improvement.

ETHICS AND DISSEMINATION

The protocol for this study was approved by the Human Research Ethics Committee of the Pontificia Universidad Católica del Ecuador (#PV-10–2022). The results of this project are socially relevant; thus, we will socialise them in several venues and formats. They will be disseminated at the CPA and in other places to reach a wider audience. A formal report will be delivered to the CPA's director and supervisors, and we plan to organise talks/workshops to present the main results to all the people working at the centre. To reach a wider audience, the results will be disseminated in peer-reviewed scientific articles, in conferences and meetings (eg, Society for Psychotherapy Research and Red Latinoamericana Psicoterapia y Cambio meetings) and plots and infographics will be shared through social media accompanied by short descriptions or explanations.

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