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Using mixed methods in feasibility studies: The example of brief transactional analysis psychotherapy for depression

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Abstract

Introduction: Few guidelines exist on how to conduct Phase 1 feasibility studies in psychological therapies. It may be theoretically argued that small-size feasibility studies are best studied with mixed methods. The primary aim of this study was to examine the feasibility of using mixed methods in feasibility studies. The secondary aim was to systematically explore the feasibility of a 16-session treatment manual in transactional analysis psychotherapy (TAP) for depression developed in a prior Phase 0 study.

Method: Nine clients received therapy from three therapists, and sample characteristics were described using flowcharts and sociodemographic statistics. Interviews were conducted with clients and therapists to explore subjective experiences of changes and processes in therapy. Psychometric instruments measured the impact on mental health, quality of life and TAP-specific outcomes. Therapist learning effects were examined through self-reported TAP-specific competencies. The analyses included reflexive thematic analysis, descriptive statistics, *t*-tests and repeated measures ANOVA.

Results: The results indicated that the clients experienced important changes, such as self-insight, better coping strategies, self-confidence and boundaries, mainly attributed to TAP and facilitated by helpful factors in TAP. Significant differences were reported in outcome measures, and analyses indicated increased competency in TAP-specific skills. No negative side effects were mentioned.

Discussion: This study provides evidence for the feasibility of TAP for depression and the feasibility of using mixed methods in feasibility studies. Future researchers may want to use similar comprehensive mixed methods designs.

KEYWORDS
clinical trial, humanistic, integrative, psychotherapy, study design

1 | INTRODUCTION

Feasibility studies are usually one of the first steps in developing new psychological interventions, to explore the feasibility of both the intervention and the study design (Carroll & Nuro, 2002; Rounsaville et al., 2001).

A feasibility study typically follows from a Phase 0 study, which may ask about the theoretical proof for the potential efficacy of an intervention, such as, 'Could this intervention work in theory?' For instance, a systematic literature review, theoretical or case study could form the theoretical foundations of a treatment manual. For example, Vos (2023) described in their Phase 0 study how they developed a new treatment manual on transactional analysis psychotherapy (TAP) for depression based on their systematic literature reviews (2021a–c). Although Phase 0 researchers indicate how a treatment may work in theory, they do not know how therapists and

clients will experience this manual and whether their hypothesised research procedures will work.

A Phase 1 feasibility study may ask about the practical proof for the potential efficacy of an intervention, such as 'Could this intervention also work in practice?' Sometimes, a feasibility study may also ask about the practical proof for the potential efficacy of research procedures (although this is usually not the study's main aim): 'Could our research procedures work?' A Phase 1 study could result in researchers concluding that the intervention and research procedures are executable or need to be adjusted. It may also be concluded that the intervention and research procedures are not feasible, for example due to the lack of support by stakeholders, practical or ethical reasons, likely negative side effects or unlikely positive outcomes. Due to the small sample size, a feasibility study may not give information about the generalisability of the findings. Instead, it may focus more on its internal validity, construct validity, fundamental data-evaluation validity, the reliability of change measured with multiple instruments, and preliminary trustworthiness of the measurement and treatment (Kazdin, 2021; Vos, 2023; see also Yardley, 2015).

Thus, a feasibility study may detect potential flaws in the intervention or study design in a small sample, which could prevent wasting time and energy and unethical practices before conducting larger studies (Kazdin, 2022; Vos, 2023). The aims and methods of Phase 1 feasibility studies should not be confused with Phase 2 pilot studies, and journal editors and reviewers may therefore want to apply different criteria for assessing their quality (e.g. requirements regarding sample size). Studies in subsequent research phases may ask about the practical proof for the actual efficacy and effectiveness of the intervention, such as, 'Does this intervention actually work in specific contexts, evaluated with the research procedures?' 'A feasibility study asks whether something can be done, should we proceed with it, and if so, how. A pilot study asks the same questions but also has a specific design feature: in a pilot study a future study, or part of a future study, is conducted on a smaller scale. As a subset of feasibility research, pilot studies may or may not be randomised and controlled'. (https://www.nihr.ac.uk/). Thus, Phase 1 feasibility studies may already include early-stage plans for future research but may not include the final future study designs. Phase 2 pilot studies are closer to the final designs of future studies and may include a clinical trial, often with a randomised control group, to try out the intervention and research procedures before these are scaled-up in larger-size Phase 3 and Phase 4 replication studies (Kazdin, 2022; Vos, 2023).

1.1 | Research aims of feasibility studies

Despite being the foundations of later research stages, there does not seem to be a clear consensus about the research aims/objectives/questions and methods of feasibility studies on psychological therapies, like there are clear frameworks for later-stage randomised controlled trials (Kazdin, 2022). We conducted a non-systematic scoping review of the 50 most cited feasibility studies on psychological therapies in Web of Knowledge and identified many research aims and objectives (see Table S1, Appendix S1). It was remarkable that many publications confused the terms 'feasibility study' and 'pilot study', often using both to describe the same study (although it could not be clearly proven, it seemed as if some authors used the term 'pilot study' to give more political weight to their study that had actually been conducted in a much earlier research stage, merely following a theoretical Phase 0 study, or even without a Phase 0 study). The mean sample size of these studies was 23.3 ($SD = 15.6$, range: 3–284). Publications that strictly focused on feasibility studies reported the following research aims regarding the feasibility of the intervention and the study procedures (based on reflexive thematic analysis of the included studies):

1. Acceptance: the extent to which all stakeholders generally accept the intervention/research, often with a main focus on ethics and potential adverse effects (this may also include an overall evaluation by the researchers of the findings regarding all other research objectives).
2. Resources: the extent to which all required resources are available for the intervention/research.
3. Outcomes: the possible range of negative and positive outcomes of the intervention/research.
4. Processes: the experience of the processes and mechanisms of change, helpful and unhelpful aspects of the intervention/research.

Implications for Practice and Policy

- The first stage of psychotherapy/counselling research includes feasibility studies, which should have clear study aims and ideally use mixed methods.
- Mixed methods can help to develop a rich understanding and cross-validation of the feasibility of the intervention and the research procedures. This study provides an example with client and therapist self-report questionnaires and open session-evaluation questions after each session, interviews with clients and therapists after the last session and a systematic case formulation.
- This study indicates the feasibility of the 16-session treatment manual in transactional analysis psychotherapy for depression. For example, clients reported important positive changes without side effects in the questionnaires, open questions and interviews, which they mainly attributed to the therapy and facilitated by helpful therapeutic factors. The promising findings should be confirmed in a pilot study and the manual could be used in structuring transactional analysis psychotherapy.

5. Improvements: the possible areas of improvement of the intervention/research.
6. Sensitivity: the sensitivity of the intervention/research to all stakeholders and their context.
7. Critical self-reflection and reflexivity regarding the intervention/research.

1.2 | Methods of feasibility studies

To achieve the varied research aims, feasibility studies have been conducted inconsistently with quantitative and/or qualitative methods. All 50 studies in our non-systematic scoping review included quantitative methods, and 18 added some qualitative methods.

1.2.1 | Qualitative

Some researchers have used qualitative methods, such as interviews, to explore and give an initial in-depth understanding of all stakeholders' subjective experiences, evaluations and narratives. This is often performed with open interview questions on a broad range of topics, like a broad fishing net, that may find information that the researchers may not have thought about and that, for example, questionnaires may not detect. However, qualitative methods may give limited information about specific, quantifiable effects and the participants' experiences of completing questionnaires. Most researchers only conduct interviews after the last therapy session, which may only reflect retrospective reconstructions of overall change; however, some studies analysed individual sessions, such as post-session interviews, and analysis of video recordings.

1.2.2 | Quantitative

Researchers may use quantitative methods to quantitatively explore topics, and give some initial indications about the effects on specific outcomes. They may also examine the feasibility of the quantitative research procedures that may be used in Phase 2/3 studies; for example, a researcher may conclude that a questionnaire is too long, complicated or insensitive for their population. The recruitment procedures may be evaluated, for example via descriptives of the sociodemographic characteristics of the sample in comparison with their target population, a flowchart of inclusion and exclusion criteria, and attrition/dropout of participants at different research stages. Some researchers use an explorative 'broad fishing net approach' (Vos, 2023), for example by using a battery of questionnaires. Others focus instead on specific instruments that only measure specific outcomes indicated by Phase 0 studies; however, it may be argued that the researcher's subjective framework may bias the selection of specific quantitative methods, and they may not detect significant findings with their specific 'fishing rod' as they may not yet know at this early research stage what outcomes may be relevant (i.e. risk of statistical bias).

Furthermore, some feasibility studies have a small sample size (less than 25), as the lack of existing evidence makes it unethical to expose a large sample to a treatment and procedures that may not be effective or may even potentially cause harm. Given the lack of power, no statistically significant effects may be expected, and the aim of using and analysing questionnaires in feasibility studies is not to test hypotheses but to explore and test questionnaires. Quantitative findings have been tentatively analysed, for example with a large significance level to be able to detect small findings in a small sample (e.g. report all findings for $p < .10$), descriptive statistics, non-parametric tests, bootstrapping, non-Bayesian analysis, individual growth trajectories, session-by-session evaluation (e.g. with Post-Session Therapy Forms), session-by-session change, and clinical and reliable improvement (Vos, 2023). Some researchers explicitly mix methods, such as asking participants to rate changes in the Client Change Interview (Elliott & Rodgers, 2008) and a therapy-specific Goal Attainment Form (Vos, 2023).

1.3 | Mixed methods feasibility study framework

In sum, most feasibility studies aim to explore the acceptance, resources, outcomes, processes, improvements, sensitivity, critical self-reflection and reflexivity regarding a new intervention and research procedures. Both quantitative and qualitative methods have strengths and weaknesses in achieving these objectives. Therefore, feasibility studies may be best studied with mixed methods that are both sensitive and specific, whereby quantitative and qualitative methods may compensate for each other's weaknesses (Landrum & Garza, 2015; Rossman & Wilson, 1985).

We believe that the research aims in feasibility studies cannot be achieved entirely by merely combining two parallel methods (Creswell & Clark, 2017). Instead, we recommend a complex mixed methods design. From the beginning, qualitative and quantitative data should be collected to develop the richest possible information set. For example, researchers should consider what other information they could collect beyond one simple pre–post-therapy questionnaire and one post-therapy interview. This may include interviews or open questions before the first session and after each session, as well as a battery of questionnaires before and after each session. The selection of questionnaires should balance sensitivity (measuring all potential outcomes) and specificity (measuring specific outcomes derived from the Phase 0 theoretical model) while keeping the length feasible for the clients, administrators and researchers. This may include interviews with all stakeholders and other relevant data, such as time investments and financial costs. Qualitative and quantitative findings must be interpreted conjointly; for example, interview information may explain questionnaire scores, and questionnaires may quantify interviews. The convergence of methods may help to answer each research objective.

It seems appropriate to base these mixed methods on a pluralistic epistemology, which regards different methods as complementary perspectives, to develop a rich holistic understanding of the intervention and research procedures (Landrum & Garza, 2015). This epistemological position may be compared with casting lights from different angles at a diamond to see as many facets as possible (Vos, 2015, 2018, 2021). Not only can the plurality of perspectives help to see more of the feasibility, but it may also help to identify which light may be the most helpful for the following stages of research.

1.4 | This study

In sum, feasibility studies are essential to therapy development, and they seem to be best studied with mixed methods. However, the before-mentioned scoping review suggested that few feasibility studies combine parallel methods, and no systematic mixed methods feasibility studies on psychological therapies exist. Thus, the therapy field lacks a clear framework and examples of mixed methods feasibility studies.

Therefore, as an example, we conducted a mixed methods feasibility study. We examined the feasibility of the new treatment manual in TAP developed in a Phase 0 study by Vos (2023). We aimed to examine the acceptance, resources, outcomes, processes, improvements, sensitivity, critical self-reflection and reflexivity of TAP. To determine whether using mixed methods may compensate for a small sample size (and thus small statistical power), we decided to conduct a small-size Phase 1 feasibility study that will be followed in the future by larger Phase 2 pilots and Phase 3/4 studies. This feasibility study aimed to achieve all research aims and objectives identified in our scoping review of feasibility studies. In the discussion section of this article, we will also reflect on the feasibility of using mixed methods in feasibility studies, by reflecting on its acceptance, resources, outcomes, processes, improvements, sensitivity, critical self-reflection and reflexivity. Thus, this article may be described as a scientific frame story: we examine the feasibility of TAP and the feasibility of using mixed methods in feasibility studies.

2 | MATERIALS AND METHODS

Table S1 shows the research aims and objectives derived from the scoping review of previous feasibility studies on psychological therapies. This table also shows how we selected qualitative and quantitative methods to answer each aim/objective. We tried to mix methods for each aim/objective, but this was not always possible (e.g. critical reflection and reflexivity were difficult to quantify). This section will describe the intervention and research procedures we aimed to evaluate in this feasibility study. We also describe the qualitative and quantitative tools and analyses.

2.1 | Intervention

Transactional analysis psychotherapy has evolved from the work of Eric Berne in the 1950s as a therapeutic approach integrating psychodynamic and behavioural concepts with an underlying humanistic philosophy (Vos & Van Rijn, 2021a). Despite many TAP training institutions and trained TAP therapists, there is only a relatively small number of 41 clinical trials, indicating moderate to large positive effects on the client's level of psychopathology, social functioning and general well-being (Vos & Van Rijn, 2024). However, the variation between trial effects was considerable, possibly due to the lack of semi-standardised treatment manuals. Developing transparent testing manuals that can be repeated (Norcross et al., 2007) is critical to proving the evidence basis of TAP.

Previous systematic reviews and meta-analyses have summed up the standard conceptual model of TA publications, matching a survey suggesting agreement among TA-practitioners, as follows (see Vos & Van Rijn, 2021a, Vos & van Rijn, 2021b, 2021c; Vos & Van Rijn, 2022, Vos & Van Rijn, 2024, for study details and differences between TA-schools). Causal TA models highlight the mix of factors potentially causing and shaping the growth of clinical issues: early life core messages (e.g. parental or generational messages, stroke balance and growth problems), life-events (e.g. experiences and traumas), ignoring existential givens (e.g. poorly learned coping with freedom, meaning, mortality and vulnerability), genetics/temperament and reactions/choices to these causal factors. The main clinical phenomenon concerns ego-states, which are distinct states/modes that a person may experience; the ego states with the most evidence are called Critical Parent, Nurturing Parent, Adult, Adapted Child and Free Child. Mental health issues are linked to a more dominant Critical Parent and Adapted Child and less dominant Nurturing Parent, Adult and Free Child. Also, TA's clinical model focuses on the life positions of I'm OK/not-OK, which the broader literature describes as self-efficacy, and others are OK/not-OK, which is defined as social functioning. Therapists aid clients by analysing these causal and clinical phenomena, offering a treatment structure (e.g. therapy goals, teaching the TA-model and therapy stages), working intensely in the present and offering a positive client-therapist bond. TA therapy has improved psychopathology, distress, self-realisation (ability to live a meaningful and satisfying life), general well-being, behavioural well-being and quality of life.

To tackle this gap, Vos (2023) systematically created a semi-structured 16-session treatment manual for brief transactional analysis psychotherapy (BTAP) for mild and moderate depression (see summary in Table S1). TAP was deemed relevant, in line with previous TA studies on depression (Fetsch, 1980, Benedetti et al., 2020; Vos & Van Rijn, 2021a; Widdowson, 2013); for example, research shows that people with depression are more likely to report an 'I'm not OK' life position, a dominance of the Critical Parent and Adapted Child, and less dominant Adult, Nurturing Parent

and Free Child ego states (Vos & Van Rijn, 2021c). According to TA theory and an international survey among TA therapists, TAP may ease depression by addressing these ego states and life position, tackle their causes, offer a therapeutic structure and constructive therapeutic relationship (Vos & Van Rijn, 2021a). This BTAP-treatment manual could be seen as a common foundation of TAP, as it was based on an international survey of TA therapists, a systematic literature review of TA psychometric tools and meta-analyses of TA clinical trials (Vos, 2023; Vos & Van Rijn, 2021a, 2021c). Specifically, the manual was based on an evidence-based conceptual model of TA (Vos & Van Rijn, 2021b), helping clients to improve via 16 sessions in four stages: initial assessment and therapeutic agreement ('contract'), systematic assessment, experiential processing, decision-making and applying script changes. Primary outcomes included mental health (depression, anxiety and general stress); secondary outcomes included general quality of life and TAP-specific outcomes that were derived from the theoretical Phase 0 study (e.g. improved ego state functioning; see details below).

2.2 | Research procedures

Participants/clients were recruited in a community psychotherapy/counselling clinic based in a training institution in the United Kingdom. Clients approached the clinic in a usual way, that is, self-referral or referral by their healthcare professional, and were assessed by a trained clinical assessor (see procedures: Vos et al., 2022). If the client met the study's inclusion criteria, they were offered further information about the study. Clients who did not meet the inclusion criteria or decided not to participate received care as usual. They proceeded with treatment within the clinic (humanistic or relational therapies).

Inclusion criteria included mild or moderate depression. Exclusion criteria were severe anxiety, severe cognitive or linguistic limitations that may hinder therapy, or other clinical presentations. Criteria were checked in a clinical interview and with Patient Health Questionnaire-9 (PHQ-9)/General Anxiety Disorder-7 (GAD-7).

Therapists were students in the final year of a master's in TAP. They had at least 100 hours of clinical placement experience. All therapists received a detailed TAP treatment manual (Vos, 2023) and 2 days of training on its use and application. They attended monthly clinical supervision by a TA experienced clinical supervisor. The relevant ethics committee provided approval.

2.3 | Qualitative methods

2.3.1 | End-of-therapy interviews

Clients were interviewed using the Client Change Interview (Elliott & Rodgers, 2008). We selected this mixed methods standardised interview schedule as it makes the findings comparable with other studies on psychological therapies. We adjusted the questions for therapists. The interview schedule included questions about the general experience, significant moments, positive, negative, lacking, expectancy, likelihood, importance, attribution of changes, helpful, unhelpful, potentially helpful aspects, missing aspects and research experiences. See interview schedules in Table S2.

2.3.2 | Post-session evaluation

After each session, clients evaluated the session via the Client Post-Therapy Form, with open questions inspired by the Client Change Interview: topics discussed in the session, important or significant moments, helpful aspects, unhelpful aspects in the session, aspects that were difficult but helpful and suggestions for improvement. After each session, therapists completed a Therapist Post-Therapy Form with the same questions and the option to describe any adjustments or deviations from the treatment manual.

2.3.3 | Case formulation

To explore the extent to which therapists adhered to the case formulation described in the treatment manual and to develop in-depth insight into the individual cases, the therapists were asked to write the case formulation according to the structure of the treatment manual (as described in Vos, 2023).

2.3.4 | Qualitative analysis

The interviews, open questions and case studies were analysed with reflexive thematic analysis, a frequently used qualitative analytical method in psychological therapies, to identify common themes across individuals, aided by critical self-reflection and reflexivity. Braun and Clarke (2022) described seven steps: transcription; reading and familiarisation; coding; searching for themes; reviewing themes; defining and naming themes; and finalising analysis.

2.4 | Quantitative methods

2.4.1 | Sample characteristics

Sample characteristics included the number of eligible clients, participants at the start and end of therapy, and the number of sessions attended, cancelled and not attended. In line with a previous study in the same clinic (Vos et al., 2022) and the British National Health Service (NHS), questions were asked at baseline about the following sociodemographic characteristics (treated as categorical/nominal variables, except if otherwise mentioned): gender (female/male/

other); age (number); employment (employed/unemployed/retired or sick/student/other); ethnicity (standard ethnic groups/open answer option); living situation (alone/partner/children/family/other); marital status (single/married/divorced/widowed/living together/other); children (number); medication (yes/no, if yes: open question); previous therapy (number of therapy round); religion (common religions/open answer option); sexual orientation (heterosexual/homosexual/bisexual/other); and receiving benefits (yes/no).

2.4.2 | Primary outcomes

The following weekly online measures were selected as standard self-report inventories frequently used in routine outcome monitoring (ROM), such as the British NHSe (Peterson & Fagan, 2017). We expected a significant decrease in all scores, but with larger effects on depression as this was the main focus of the treatment manual. We used standardised reliable change indices (RCIs) for the questionnaires in the general population, which adds benchmarking as a way to evaluate the effectiveness or iatrogenic effects and would allow a comparison of the outcomes with national benchmarks and thus probably support the effectiveness of TAP despite the small study design.

Depression

The PHQ-9 is a validated, reliable, nine-item questionnaire that examines the severity of depression symptoms on 4-point Likert scales (Kroenke et al., 2001). Respondents rated how bothered they have been by a range of problems over the last 2 weeks, such as feeling down, tired, depressed or having sleep problems. Total scores are interpreted as no (0–4), mild (5–9), moderate (10–14), moderately severe (15–19) or severe depression (20–27). For the PHQ-9, 6 points or more change is often considered reliable (based on the NHS Improving Access to Psychological Therapies programme). Baseline Cronbach's alpha in this study was .81, Spearman–Brown was .91 for split-half reliability.

Anxiety

The GAD-7 is a validated, reliable, 7-item questionnaire that examines severity of anxiety symptoms on 4-point Likert scales (Kroenke et al., 2007). Respondents rated how bothered they have been by difficulties, such as feeling anxious and worried: total scores of 0–5 present mild, 6–10 moderate, 11–15 moderately severe and 15–21 severe anxiety. For the GAD-7, 5 points or more change is often considered reliable This study's Cronbach's alpha was .88, and Spearman–Brown was .90.

General stress

The Clinical Outcomes in Routine Evaluation-10 (CORE-10) is a validated, reliable, 10-item questionnaire that measures symptoms of psychological distress on 5-point Likert scales (Barkham et al., 2013). The clinical cut-off score for general psychological distress was 11.0, and for depression, 13. For the PHQ-9, 6 points or more change is often considered reliable (based on the NHS Improving Access to Psychological Therapies programme). This study's Cronbach's alpha was .83, and Spearman–Brown was .87.

2.4.3 | Secondary outcomes

To measure the effects of generic therapy, clients were asked to complete the following questionnaires before the first session (post-assessment) and after the last therapy session to measure general quality of life and specific effects theoretically expected on the basis of the Phase 0 studies. The *Work and Social Adjustment Scale* (WSAS) and WHOQOL-BREF were selected as these are frequently used measures of general effects on quality of life, and the *Life Position Scale* (LPS), *Acceptance and Action Questionnaire* (AAQ-II) and *Schema Mode Inventory* (SMI) were selected as they measured TAP-specific concepts with valid, reliable instruments (see review of TAP instruments in Vos & Van Rijn, 2021b). Based on the therapeutic conceptual model of TAP (Vos & Van Rijn, 2021c), we expected that clients would have better quality-of-life scores (WSAS, WHOQOL-BREF and all *Ryff's Well-being Scale* [RWBS] subscales), be more accepting of their experiences (AAQ-II), exhibit more positive life positions towards oneself and others ('I am OK', 'Others are OK', in TA terms), decreased Vulnerable/Angry/Enraged/Undisciplined Child, increased Contented Child, and decreased Punitive/Demanding Parent and increased Healthy Adult (SMI).

Work and social adjustment scale

This validated, reliable, 5-item questionnaire measures the impact of mental health problems on daily-life functioning, with 8-point Likert scales (Thandi et al., 2017). This study's Cronbach's alpha was .84 and Spearman–Brown was .87.

WHOQOL-BREF

This validated, reliable, 26-item questionnaire measures quality of life regarding physical, psychological, social and environmental health on 5-point Likert scales (Ilić et al., 2019; Oliveira et al., 2016). Due to large correlations, lack of statistical differences across scales and large overall reliability (Cronbach's alpha = .80, Spearman–Brown = .82), we only used total scores.

Ryff's well-being scale

This validated, reliable, 42-item questionnaire measures the well-being domains of autonomy, environmental mastery, personal growth, positive relationships, purpose in life and self-acceptance on 6-point Likert scales (Abbott et al., 2010). This study's respective Cronbach's alphas were .83/.86/.92/.80/.77/.82, and Spearman–Brown were .84/.87/.90/.85/.78/.81.

Life position scale

Life positions describe an underlying position towards self and others, developed in childhood and forming a largely unconscious relationships framework. This validated, reliable, 20-item questionnaire measures the life positions of the subscales 'I am OK/not-OK' and

'others are OK/not-OK' on 5-point Likert scales (Boholst, 2002; Vos & Van Rijn, 2021b). This study's Cronbach's alphas of subscales were, respectively, .81/.85, and Spearman–Brown coefficients were .83/.85.

Acceptance and action questionnaire

This validated, reliable, 7-item questionnaire measures acceptance of experiences on 7-point Likert scales (Bond et al., 2001). This study's Cronbach's alpha was .78, and Spearman–Brown was .80.

Schema mode inventory

This validated, reliable, 124-item questionnaire with 6-point Likert scales measures schema modes, a construct inspired by TAP's ego states (Vos & Van Rijn, 2021b). The subscales include (this study's Cronbach's alpha/Spearman–Brown): Vulnerable Child (.81/.78), Angry Child (.77/.79), Enraged Child (.83/.85), Impulsive Child (.83/.87), Undisciplined Child (.85/.88), Contented Child (.85/.86), Compliant Surrender (.84/.84), Detached Protector (.84/.86), Detached Self-Soother (.85/.83), Self-Aggrandizer (.83/.82), Bully and Attack (.80/.79), Punitive Parent (.83/.80), Demanding Parent (.80/.81) and Healthy Adult (.81/.79).

2.4.4 | Therapist skills

After each session, therapists completed the Transactional Analysis Psychotherapeutic Self Report Competencies Scale (TAP-SRCS; Vos & Van Rijn, 2022). This 4-item scale asked therapists to assess each session based on the four groups of evidence-based TAP competencies (Vos & Van Rijn, 2020b): analysing clinical and aetiological phenomena, offering a structure, working at experiential depth in the here and now; creating and using a constructive therapeutic relationship. Like other competencies scales, therapists assessed how well they applied these competencies on 6-point scales.

2.4.5 | Quantitative analyses

Power

It was expected that the study was underpowered due to the small sample size; therefore, the focus lay on explorative and descriptive analyses and tests that are relatively robust for small sample sizes. Significance level was set as .05, and trends between .05 and .10 were reported to compensate for possible type-II bias. All primary and secondary outcome measures did not have large skewness (<+/−.1) or large kurtosis (<+/−3), which suggested that parametric tests could be used although the sample size was small.

Sample characteristics

Sample characteristics were described with frequencies, means and standard deviations. All baseline sociodemographic variables and PHQ-9/GAD-7/CORE-10 scores were used to predict with regression missing-value analysis: participants' participation, cancellation, not attending, not filling in a questionnaire, and specific missing values. Missing values were not imputed as this could disproportionally bias effects in a small sample. The baseline scores and effect sizes were compared between participants in this study and other clients in the clinic (regardless of their potential eligibility for this study) who had agreed to participate in the research (Vos et al., 2022).

Pre–post-therapy effects

These effects were described with Cohen's *d* (.20 considered small, .50 medium and .80 large); the effects need to be interpreted cautiously due to the small sample size (we did not expect any statistically significant effects due to insufficient power). We also calculated clinical change (i.e. number of clients above the clinical cut-off point for each scale), reliable and clinically significant change for measures with available clinical data (Jacobson & Truax, 1991; Speer, 1992).

Session-per-session changes

Repeated measures ANOVA were conducted to test weekly changes. The assumptions of repeated measures tests were tested for all questionnaires (e.g. Mauchly's test of sphericity $p > .05$). A common rule of thumb is that the number of estimations must be smaller than the number of participants; therefore, we measured changes in the means between the baseline and the end of each stage of therapy (i.e. measurements after Sessions 2, 6, 13 and 16). Effects were measured with *F* (.10 considered small, .25 medium and .40 large). Post hoc pairwise comparisons using Bonferroni correction were conducted to test differences between measurement moments. Bootstrapping with 5000 rounds was used as a robust estimation of effect sizes.

Therapist skills

We analysed differences between baseline and post-therapy with *t*-test/Cohen's *d* and analysed changes over all sessions via repeated measures ANOVA.

3 | FINDINGS

3.1 | Sample

Figure 1 provides a sample flowchart. Forty-five individuals were assessed as routine in the clinic, of whom 17 (37.7%) were eligible and invited (see Table 1 and Table 2). Nine individuals (52.9%) participated and completed all baseline measures. Eight received all 16 sessions and one 14 sessions as she cancelled two sessions. Seven individuals (77.7%) completed questionnaires immediately post-therapy, and four (57.1%) at 3-month follow-up. Six clients (66.6%) and all three therapists agreed to an interview. No baseline measures significantly predicted participation rates and the likelihood of completing questionnaires. As described below, no significant differences were found in baseline and change scores between individuals

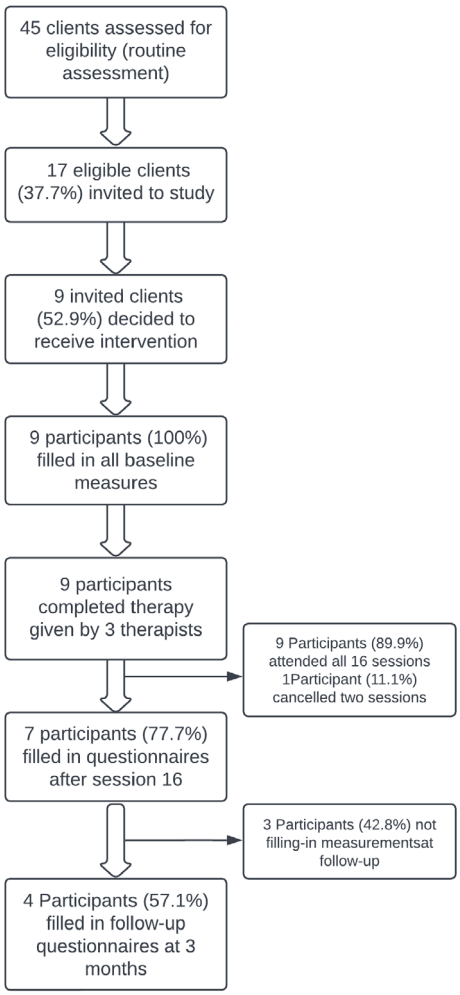

FIGURE 1 Flowchart.

participating in this trial and other clients in the community clinic (i.e. all clients, regardless of eligibility for this study).

3.2 | Qualitative findings

3.2.1 | End-of-therapy interviews

The common themes identified in interviews are shown in Table 2; the most frequently reported themes will now be highlighted. Clients described their general therapy experience by referring to their development of greater self-understanding, although they also reported that there was more to learn. Therapists reported that the manual structure had helped the clients to progress quickly and that they had learned many skills in a steep learning curve. Both clients and therapists reported that the most significant moments in therapy regarded developing self-insight into influences of early life experiences on present problems, acknowledging unhelpful relational patterns, sharing the case formulation and framing problems with the TAP theoretical framework. Clients reported that they had experienced large, important and mainly unexpected changes, which they mainly attributed to therapy, and therapists similarly observed in clients large, important changes which they attributed to TAP. According to therapists and clients, these changes included greater self-understanding, emotional coping strategies, better boundaries, self-confidence and self-compassion. No negative or unwanted changes were reported. Clients found it helpful in therapy to develop self-insight into the causes of their behaviour and emotions, although they also reported this was often painful in the short-term and that they could see better what are helpful and unhelpful responses. Therapists mainly found the systematic assessment, sharing of case formulations and exploring the clients' early life experiences helpful. Both clients and therapists found therapy too short, with some remaining issues to work on. On self-reflection. the therapists reported that in future, they would have more confidence in themselves as therapists, better individually tailor TAP, use countertransference better, and be more flexible and balanced following the treatment manual with being in the therapeutic relationship. Clients had no comments on the research experiences except on time-consuming questionnaires. Therapists said the research helped them work more systematically, apply theory better in practice and grow therapeutic confidence, although also felt the questionnaires were time-consuming.

3.2.2 | Post-session evaluation

Seven clients completed post-therapy questionnaires for each session, and all three therapists completed post-therapy questionnaires for each session with each of the seven clients. Table S1 shows an overview of the therapy stages/sessions and the themes identified in the answers of the therapists and clients for each stage/session. An informal comparison suggested that the answers of therapists and clients were relevant to each therapy stage. No comments seemed completely irrelevant or out-of-phase. The therapists only reported minor deviations and adjustments from the treatment manual. Therapists mainly seemed to struggle with applying the manual flexibly and not in a too directive way to clients and tailoring it to the client's unique tempo. However, they acknowledge that this flexibility improved over the sessions, possibly due to increased therapist confidence. Clients struggled mainly with facing difficult emotions and memories, although they admitted this was helpful in the long term.

3.2.3 | Case formulation

Two therapists provided complete case formulations for five clients, and completed the standardised case formulation form (one had not accurately recorded this due to personal circumstances). Table S2 shows an overview of the case formulations, indicating the relevance of all themes to the case formulation. However, as the treatment manual hypothesised, the number of themes discussed was relatively small, and therapists did not seem to generate a large diversity of hypotheses. In the interviews, two therapists said that the reported case formulation was a concise version provided for research purposes, whereas, in their

TABLE 1 Sociodemographic characteristics.

	Frequencies
Gender	4 women 1 man
Age	Mean = 38 years, *SD* = 6.0 years
Employment	2 part-time employed 2 full-time employed 1 self-employed
Ethnicity	2 White British 2 Other White 1 Other Asian
Living situation	2 alone 3 with partner
Marital status	2 married 1 divorced 2 single
Children	3 no children 2 two children
Medication	5 none
Previous therapy	1 previous therapy 4 first therapy
Religion	1 Christian 4 none
Disability	5 none
Sexual orientation	1 bisexual 4 heterosexual

clinical notes, they had more hypotheses; thus, these themes may not comprehensively reflect all components therapists considered (i.e. asking therapists to fill in the standardised case formulation may not be the most comprehensive way to collect all relevant case details).

3.3 | Quantitative findings

3.3.1 | Primary outcomes

Repeated measures ANOVA was conducted to test changes in the means between the baseline and end of each stage of therapy (see Figures 2–4).

Depression

The mean PHQ-9 scores changed significantly over time ($F[4, 16] = 10.143$, $p < .001$). Post hoc pairwise comparison did not show any significant differences between the baseline and the end of the initial contact and assessment therapy stages but showed a significant decrease in scores between the baseline and the end of the experiential processing stage ($p = .011$) and the final session ($p = .018$). The pre–post-therapy change (i.e. difference between baseline measurement before the first session and the questionnaire after the last session) was large (Cohen's $d = 3.97$, $p < .002$). Both clients with baseline scores of moderate depression (PHQ-9 scores 5–9) had post-therapy moderate depression; of the three clients with moderate baseline depression (PHQ-9 scores 10–14), two were no longer depressed, and one had mild depression post-therapy; both clients with baseline moderately severe depression (PHQ-9 scores 15–19) had mild depression post-therapy. Closely similar to the population RCI of 6 points (NHS Improving Access to Psychological Therapies), based on the post hoc calculation of RCI in this sample, the change was considered reliable if the change was larger than 5.72 (based on baseline reliability of .56 and *SD* of 3.11), which was reached in four out of seven individuals (57.1%). Four out of seven individuals (57.1%) also showed clinically significant change in depression.

Anxiety

The mean GAD-7 scores differed significantly across time points ($F[4, 16] = 3.366$, $p = .035$). Post hoc pairwise comparison did not show significant differences between the baseline and the first two therapy stages, but there was a statistical trend that scores were lower than the baseline at the stage of experiential experimentation ($p = .06$) and final session ($p = .07$). Pre–post-therapy change was large (Cohen's $d = 2.82$, $p = .013$). Of all three clients with baseline mild anxiety (GAD-7-scores: 6–10), two were not anxious, and one remained mildly anxious post-therapy; of the four clients with baseline moderately severe anxiety (GAD-7: 11–15), three had become mildly anxious, and one was no longer anxious. Based on the post hoc calculation of RCI in this sample, change was considered reliable if the change was larger than 3.14 (based on baseline reliability of

TABLE 2 Themes in interviews with clients and therapists.

Construct	Client interview	Therapist interview
Number of participants	6	3
General experience	3 Greater self-understanding 2 I can still learn more 1 Take control of my own life 1 More self-compassionate 1 Better boundaries 1 Emotional coping strategies	3 structure of treatment manual helped to move quickly to essential tasks and achieve client progress 2 one of the best experiences I have had in my training and practice as a therapist 2 Learning many new highly valued therapist competences 2 Large learning curve in giving therapy 1 client not fit for therapy (focus was anxiety) 1 working in the relationship helped clients 1 client struggled with being in therapy as this was their first therapy experience 1 clear stages and tools 1 negative ideas about semi-structured therapy has proven wrong
Significant moments	4 sharing case formulation 3 self-insight into influences of early life experience on the present 3 self-insight into unhelpful relational patterns 2 theoretical explanations 1 filling-in questionnaires	5 sharing case formulation with client 4 self-insight into influences of early life experience on the present 3 self-insight into unhelpful relational patterns 3 theoretical explanations 1 filling-in questionnaires
Positive change	4 greater self-understanding 2 better self-confidence 2 better emotional coping strategies 1 better boundaries 1 more self-compassionate 1 less anxiety 1 less depression	3 more self-awareness of cause of mental health problems 3 emotional processing 2 expressing of needs and wants in relationships 1 Identifying and changing unhelpful ego-states and victim positions in daily life 1 developing a sense of future they want
Negative change	4 none 1 bereavement about death of loved one	3 none
Lack of change	1 More confident (although some confidence achieved)	3 Nothing 1 During therapy new goals emerged 1 Severe anxiety in one client
Expectancy of change	2 Somewhat surprised by these changes 1 Neither expected nor surprised 1 Somewhat expected these changes	2 Somewhat surprised by these changes 1 Neither expected nor surprised
Likelihood of change	3 very unlikely that these changes would have happened without therapy 1 neither likely nor unlikely that these changes would have happened without therapy 1 somewhat likely that these changes would have happened without therapy	3 very unlikely that these changes would have happened without therapy
Importance of change	4 extremely important 1 moderately important	3 extremely important
Attributions	3 reflecting on self with the therapist 1 sharing experiences 1 interaction between therapy and changes in daily life 1 don't know	2 systematic approach of the manual 2 emotional processing of childhood experiences 1 strong therapeutic relationship 1 time limit 1 clinical supervision

TABLE 2 (Continued)

Construct	Client interview	Therapist interview
Helpful aspects	3 developing self-insight into the causes of behaviour and emotions 2 better seeing what are helpful and unhelpful ways to cope with situations 1 everything 1 therapy goals 1 exploring early life 1 exercises 1 theory explanation 1 repairing rupture in therapeutic relationship 1 experiment with alternative behaviour 1 accept my wishes in life	2 systematic assessment 2 sharing of case formulation 2 explorations of early life experiences, both positive and negative 1 sharing theory 1 questionnaires to develop holistic understanding 1 fast pace
Unhelpful aspects	1 some exercises triggered some anxiety 1 therapist seemed going off-track of what I wanted	2 quick pace 1 homework and experiential processing did not apply to one client
Difficult but potentially helpful aspects	5 confrontations with early life memories 2 shame about unhelpful behaviour 1 realising unfulfilled wishes in life	2 reflecting on early life experiences 2 reflecting own unhelpful behaviour 1 emotional processing 1 some clients resisted questionnaires
Missing aspects & recommendations for improvement	4 too short 4 remaining topics to work on 1 more reading 1 mediation therapy	1 more information about clients at risk 1 therapy goal forms may be better explained 1 facilitate therapist peer support 1 more practice with flexibly applying the treatment manual
Future applications		3 more confidence in myself as therapist 2 better tailor therapy to client 2 better use of countertransference 2 accept my own uncertainty 2 taking less time for activities 1 balance between following treatment manual and therapeutic relationship 1 understanding depression as cover of unexpressed feelings 1 focus more on emotions than thoughts
Research experience	2 time-consuming questionnaires	2 learned to work more systematically 2 learned to apply theory better in practice 2 time consuming research forms 2 growing confidence 1 focus on client goals 1 helpful training days 1 suggestion to facilitate more peer support

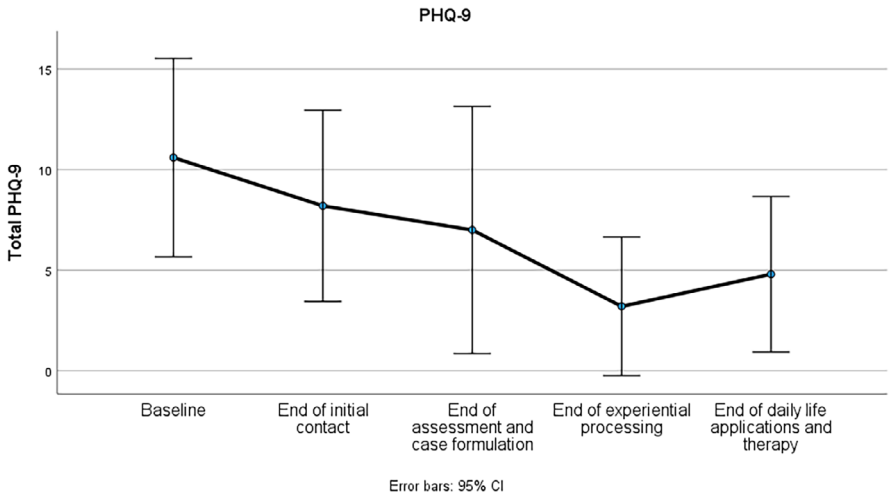

FIGURE 2 Outcomes on Patient Health Questionnaire-9 (PHQ-9) at the end of each therapy stage (depression).

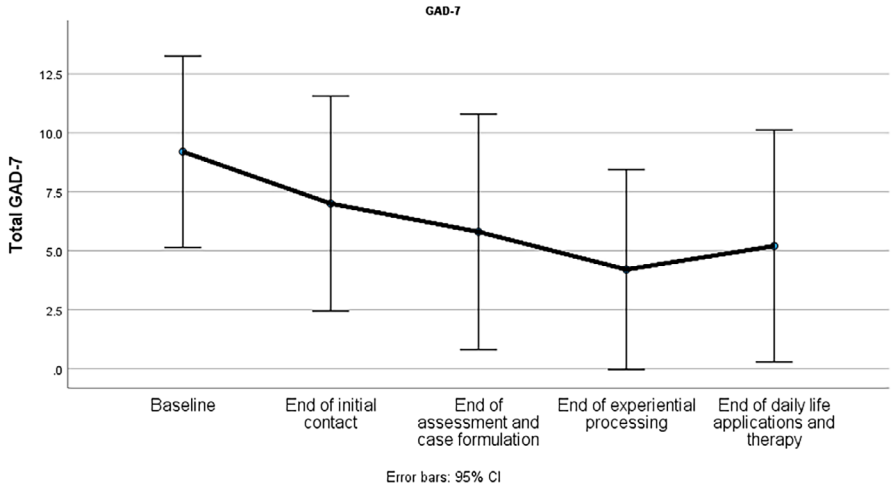

FIGURE 3 Outcomes on General Anxiety Disorder-7 (GAD-7) at the end of each therapy stage (anxiety).

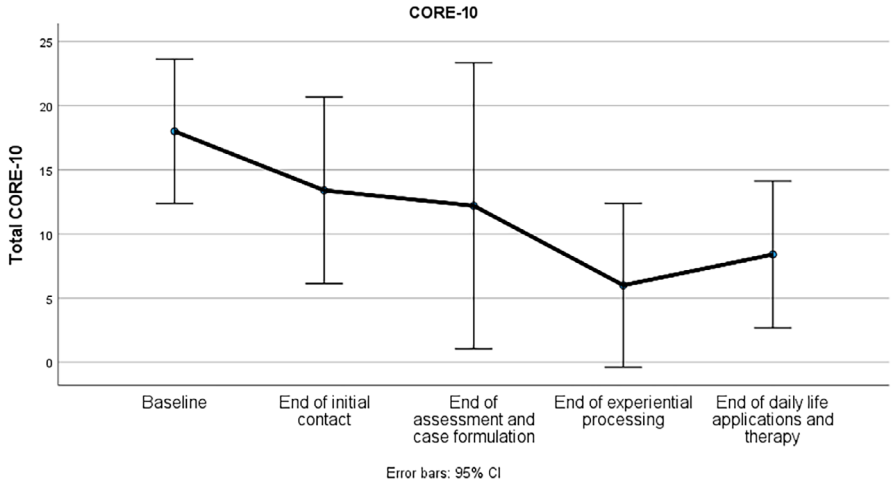

FIGURE 4 Outcomes on Clinical Outcomes in Routine Evaluation-10 (CORE-10) at the end of each therapy stage (general distress).

.88 and *SD* of 3.27), which was reached in four out of seven individuals (57.1%). However, the population RCI was slightly larger with 5 points, but the outcomes did not differ, as this was still reached in the same number of four individuals (NHS Improving Access to Psychological Therapies). Three out of seven clients (42.85%) showed clinically significant change in anxiety.

General stress

The mean CORE-10 scores differed significantly over time ($F[4, 18] = 8.514$, $p < .001$). Post hoc pairwise comparison did not show significant differences between baseline and the first two therapy stages but showed a significant decrease between baseline and the end of the experiential processing stage ($p = .013$) and the final session ($p = .004$). Pre–post-therapy change was large (Cohen's $d = 3.96$, $p < .001$). Four of all seven clinically distressed clients at baseline (CORE-10 >11) were no longer clinically distressed post-therapy. Closely similar to the population RCI of 6 points (NHS Improving Access to Psychological Therapies), based on the post hoc calculation of RCI in this sample, the change was considered reliable if larger than 6.39 (based on baseline reliability of .75 and *SD* of 4.61), which was reached in four out of seven individuals (57.1%). Four out of seven individuals (57.1%) also showed clinically significant change in distress.

3.3.2 | Secondary outcomes

The WSAS, WHOQOL-BREF and RWBS tested quality of life. Five clients completed WSAS at baseline and post-therapy (Cronbach's alpha = .87, .92). There was a significant decrease in WSAS-impairment ($M = 14.8$, $SD = .9.80$; $M = 12.00$, $SD = 10.88$, Cohen's $d = 1.50$, $p = .014$). One client had remained moderate-severely impaired (WSAS >20); both clients with baseline mild impairment (WSAS 10–20) were no longer impaired (WSAS <10); one client remained unimpaired. Four individuals at baseline completed the WHOQOL-BREF at a level comparable with a psychiatric population ($M = 77.25$, $SD = 14.95$), and post-therapy, it significantly improved (Cohen's $d = 5.16$, $p = .002$) to a level equivalent with students ($M = 89.25$, $SD = 13.05$; Ilić et al., 2019; Oliveira et al., 2016). Five individuals completed the RWBS at baseline and post-therapy; they reported significant improvement in self-acceptance ($M = 24.25$, $SD = 2.21$; $M = 28.25$, $SD = 2.62$; Cohen's $d = 2.94$, $p = .036$),

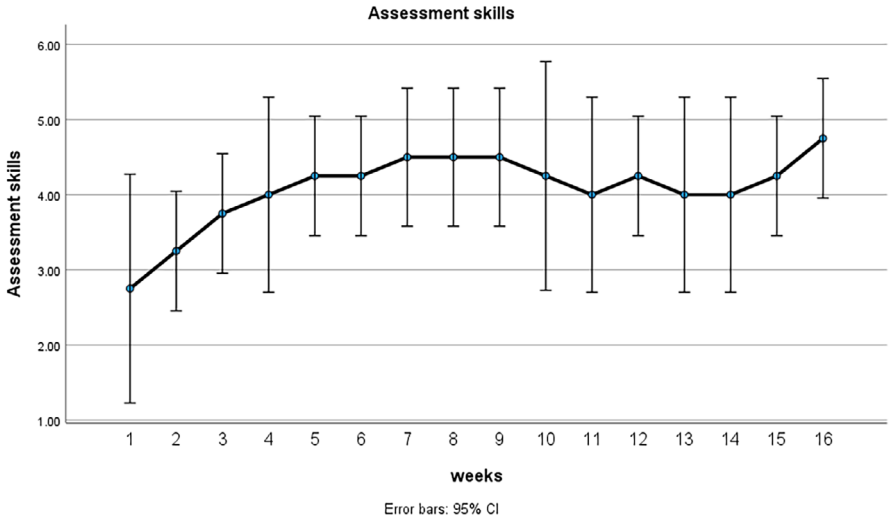

FIGURE 5 Changes in therapists' assessment skills.

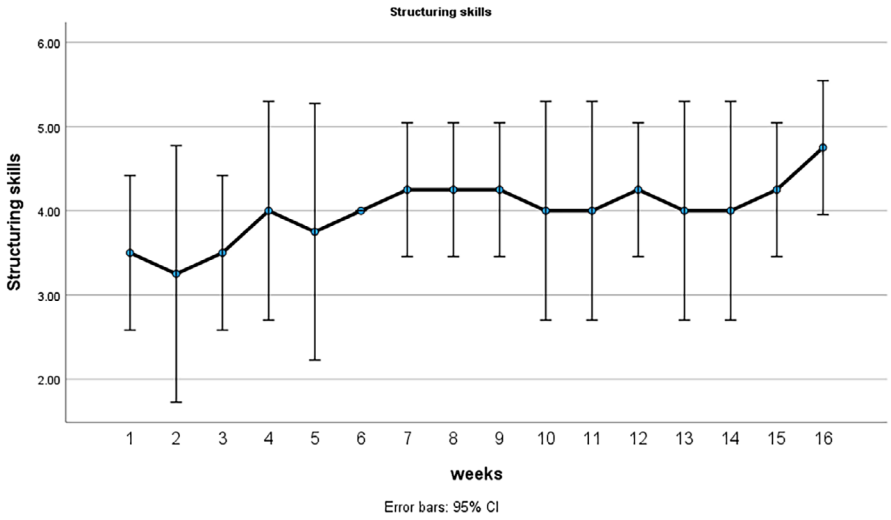

FIGURE 6 Changes in therapists' structuring skills.

environmental mastery ($M = 24.25$, $SD = 3.68$; $M = 28.50$, $SD = 3.31$; Cohen's $d = 3.30$, $p = .04$); there were no significant changes in autonomy, growth, relationships and purpose. When one individual with high baseline anxiety was removed, the effect sizes were larger, and there was a trend of improved relationships ($M = 25.67$, $SD = 1.15$; $M = 21.66$, $SD = 1.15$; Cohen's $d = 1.52$, $p = .06$), Overall, these scales indicate significant improvement in several quality-of-life domains.

The AAQ-II was completed by four individuals, showing an improvement in experiential acceptance ($M = 28.00$, $SD = 9.05$; $M = 29.75$, $SD = 11.70$; Cohen's $d = 3.09$, $p = .002$). The LPS was completed by four individuals, showing a large improvement in the life position towards oneself ('I am OK' scale total: $M = 29.00$, $SD = 5,34$; $M = 37.00$, $SD = 4.08$; Cohen's $d = 5.41$, $p = .002$), and a small improvement in the large position towards others ('others are OK' scale total: $M = 37.00$, $SD = 6.97$; $M = 38.50$, $SD = 3.69$; Cohen's $d = 5.30$, $p = .002$); at post-therapy, scores were similar to healthy students (Boholst, 2002). Four individuals completed the SMI at baseline and post-therapy, showing a significant increase in their Healthy Adult functioning (from moderate, $M = 3.9$, $SD = .34$, to high, $M = 4.5$, $SD = .46$; Cohen's $d = 3.5$, $p = .002$), a significant decrease in their Undisciplined Child (from high, $M = 3.25$, $SD = .98$, to average, $M = 3.04$, $SD = .99$; Cohen's $d = 2.50$, $p = .008$), and a trend of a more Healthy Child (from moderately high, $M = 3.45$, $SD = 1.09$, to high, $M = 4.17$, $SD = .55$; Cohen's $d = .70$, $p = .07$) and less Vulnerable Child (from high, $M = 3.25$, $SD = .74$, to moderate, $M = 2.57$, $SD = .09$; Cohen's $d = .85$, $p = .09$). All other SMI scales had moderate scores and remained unchanged. In sum, these changes in AAQ-II, LPS and SMI seemed to indicate several effects as hypothesised by the conceptual therapeutic model of TAP.

3.3.3 | Therapist skills

Between the first and last sessions, therapists had significantly improved their competences regarding assessment (Cohen's $d = 2.0$, $p = .006$), structuring (Cohen's $d = 1.41$, $p = .017$), experiential (Cohen's $d = 1.05$, $p = .039$) and relational skills (Cohen's $d = .95$, $p = .05$). Repeated measures ANOVA were conducted for all 16 therapy sessions on the TAP therapist competencies. Assessment skills

improved significantly ($F[15, 45] = 4.65$, $p < .001$), as well as structuring skills ($F[15, 45] = 2.31$, $p = .015$) and experiential skills ($F[15, 45] = 3.18$, $p = .001$); there was a trend of improvement in relational skills ($F[15, 45] = 1.76$, $p = .071$). Post hoc comparisons indicated that the largest learning curve for all skills happened in the first five sessions. See Figures 5–8.

4 | DISCUSSION

This study told a frame story, with findings relevant to understanding the feasibility of TAP, as well as using the frame of mixed methods to understand TAP's feasibility into psychological therapies.

4.1 | Feasibility of TAP treatment manual

The discussion will first focus on systematically answering the research aims for TAP, based on the mixed methods as described in Table S1, finalising with conclusions about TAP's acceptance.

4.1.1 | Outcomes

The interviews indicated that clients experienced large, important changes in their lives and no negative changes. Despite the small sample, significant positive effects were found on the primary outcomes of depression, anxiety and general stress; as expected, the effects on depression were largest, and the therapy seemed less fit for the one client who reported high baseline levels of anxiety (this seems to suggest that this manual may not work as well for clients whose primary mental health issues concern anxiety). The secondary outcomes seemed as expected, regarding improving general quality of life, ego states and life position; this may be cautiously interpreted as suggesting that the treatment processes functioned as hypothesised.

t-tests did not reveal any differences in baseline scores, statistical and clinical effects, with other humanistic and relational therapies in the same clinic, as published elsewhere, showing similar reliable and clinically significant improvement (79.9%/38.9% for PHQ-9, 61.6%/54.8% for GAD-7 and 59.1%/48.9% for CORE-10, respectively; these outcomes were comparable to British NHS data; Vos et al., 2022). The

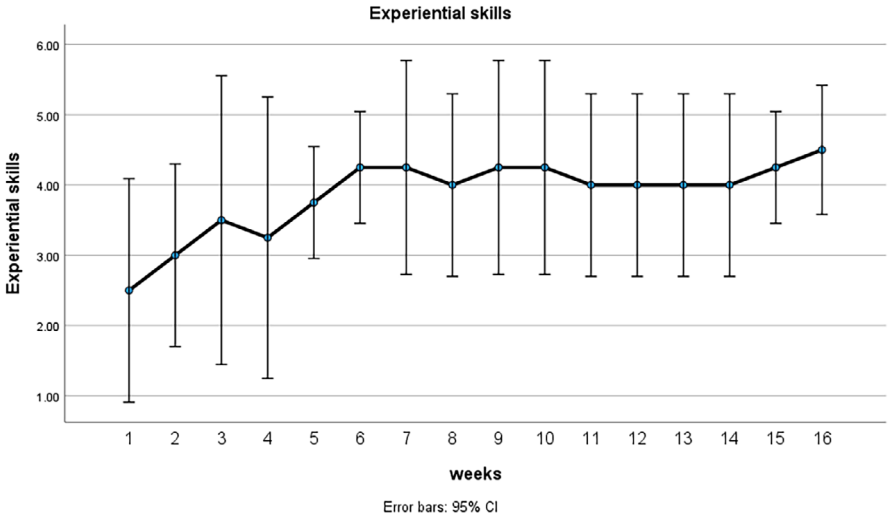

FIGURE 7 Changes in therapists' experiential skills.

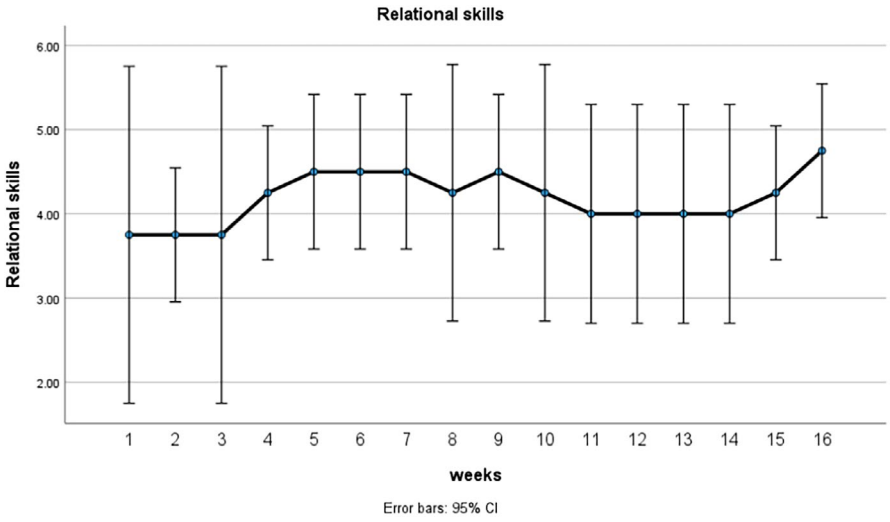

FIGURE 8 Changes in therapists' relational skills.

TABLE 3 Recommended protocol for feasibility studies based on transactional analysis psychotherapy (TAP) Phase 1 Study.

General research aim[a]	Specific research objective[a]	Examples from previous research[a]	Qualitative method	Quantitative method
Study design				
Formulate research objectives about feasibility		• Acceptance • Required resources • Outcomes • Treatment and research processes • Treatment and research recommendations for improvements • Sensitivity to change • Researcher's critical self-reflection and reflexivity.		
Prepare the feasibility study	Completed Phase 0 study ('could this work in theory?')	• Systematic literature review on the treatment objective (e.g. depression), outcomes of interventions in this group (e.g. meta-analyses of therapies for depression), evidence for the common aetiology, clinical phenomena, therapeutic mechanisms, the role of the therapist client and therapeutic relationship, outcomes and therapeutic competencies in the specific intervention in other populations (e.g. conceptual review and meta-analysis of TA clinical trials) • Surveys, interviews or focus groups with stakeholders; generic evidence-based therapeutic competencies (e.g. common factors).		
Prepare a treatment manual or intervention guidance (phase 0)	Develop a treatment manual based on literature and stakeholder perspectives.	Consider: • Eligibility of clients • Eligibility of therapists (e.g. required competencies, training) • Procedures for assessment, diagnosis or case formulation • Conceptual model: common aetiology, clinical phenomena, therapeutic mechanisms, the role of the therapist, client and therapeutic relationship; ideally, a causal model • Therapeutic goals and expected outcomes • Risk management (e.g. distress and suicidal ideation protocols) • Treatment phases • General structure of sessions within the phases • As detailed as possible guidance of therapists, for example a session by session manual • Intervention toolkit (e.g. techniques, steps or references to handbooks that can be used) • Any assessment or intervention tools (e.g. questionnaire, assessment form) • Training of therapists (provide training) • Clinical supervision arrangements • Reflections on ethics and dual roles		
Decide sample & recruitment procedures		• Include all stakeholders, for example, clients, therapists, reception/administration staff, researchers. • Sample size: convenience sample (however, many people want to participate in a particular period); the number of clients that is ethical to give an untested intervention. • Select a sample and develop recruitment procedures for the feasibility study that is as close as possible to the later-phase trials and ideally as close as possible to clinical practice to increase the study's ecological validity.		

(Continues)

TABLE 3 (Continued)

General research aim[a]	Specific research objective[a]	Examples from previous research[a]	Qualitative method	Quantitative method
Decide overall study design	Complex mixed methods design (not merely parallel methods), based on a pluralistic epistemological position	Data collection is a balance between: • Sensitivity (measuring all potential outcomes) • Specificity (measuring specific outcomes derived from the Phase 0 theoretical model) • Keeping the length feasible for the clients, therapists, administrators and researchers	• Client Change Interviews (CCI) with therapists and clients (see table footnote) • Open questions in post-session form for therapists and clients (see footnote) • Structured case formulation form • Therapist notes	• Primary measures: baseline before the first session and after each session (e.g. mental health: depression [PHQ-9], anxiety [GAD-7], general distress [CORE-10]) • Secondary measures before the first session and after the last session, ideally with long-term follow-up at three and 6 months (e.g. treatment specific outcomes based on key therapeutic mechanisms identified in Phase 0 study; general quality of life, for example WSAS, WHOQOL, SF-6D) • Goal Attainment Form filled in in the first session and attainment evaluated in the last session • Administrative data • Time investment • Financial costs
Feasibility of the intervention				
Exploration of general acceptance of the intervention	Explicit acceptance		CCI interviews with clients and therapists	
	Critical overall summary of all other objectives		Researchers' reflections (e.g. unstructured reflection meeting by research team)	• Consider therapy satisfaction survey
Exploration of available resources for the intervention	General resources	Finances, rooms, staff, clinical skills, organisational skills, team collaboration	• CCI with therapists and administrative staff • Researchers' reflections	
Exploration of the intervention outcomes	Positive outcomes on primary outcome measures (actual or potential)		CCI with clients and therapists (e.g. any positive changes in life since therapy)	• Routine outcome monitoring for relevant primary outcomes before each session • Statistical analysis[a]
	Negative outcomes on primary outcome measures (actual or potential)	Screening for safety and adverse side effects	CCI with clients and therapists (e.g. any negative changes in life since therapy)	• Session-per-session relevant primary outcomes • Statistical analysis[a]
	Positive and negative outcomes on secondary outcome measures (actual or potential)		CCI with clients and therapists	• Measures for secondary outcomes • Statistical analysis[a]
	Range and sensitivity of outcomes		CCI with clients and therapists	Variation and size of differences of all instruments
	Relevance and significance of outcomes		CCI with clients and therapists (e.g. rating size of life changes; questions about significance)	

TABLE 3 (Continued)

General research aim[a]	Specific research objective[a]	Examples from previous research[a]	Qualitative method	Quantitative method
Exploration of the intervention processes	Processes and mechanisms of change		CCI with clients and therapists (e.g. questions about helpful factors unhelpful or problematic factors, attribution of change, significant moments)	• Scatterplots • Non-parametric associations and correlations between measures
	Sequence of session-per-session changes	Description of change (e.g. sudden, gradual and stages)	Post-Session Form for clients and therapists	• Session-per-session primary outcome measures • Goal Attainment Form after first and last sessions
	Dose-effect analysis	Frequency or intensity of sessions		• Scatterplots and non-parametric associations between the outcomes and the number of attended sessions
	Co-construction of the therapy experience	• Therapist's responsiveness and tailoring • Therapeutic relationship	Post-Session Form for clients and therapists	
	Adherence to the treatment manual or intervention guidance	Treatment fidelity checklist	Content analysis: • Post-Session Form for clients and therapists • Therapist clinical notes • Therapist's structured assessment form • Content of CCI with clients and therapists • Analysis of video or audio recordings	
	Other experiences, narratives and observations of therapy	Other process research, for example assimilation analysis; comprehensive process analysis; interpersonal process recall		
Exploration of possible areas of improvement of the intervention	Identify possible areas for improvement		• CCI with clients and therapists Post-Session Form for clients and therapists • Researchers' reflections	
Exploration of the sensitivity of the intervention	Sensitivity of the intervention to individuals and context	Case studies (e.g. all cases, critical incidents cases or ideal case studies)	• Content analysis of case formulations (ideally via a structured case formulation form) • Other client data (e.g. therapist's client record notes)	• Description of sociodemographic variables • Analysis and visualisation of trajectories of individual clients (e.g. repeated measures, growth analysis) • Description of variation on all instruments
	Sensitivity of the intervention to be applied by therapist		CCI with therapists	Description of the characteristics of therapists joining this study
	Growth of therapist' competencies (learning effect)		CCI with therapists	Session-by-session self-report of applied therapist skills therapist's Post-Session Form

(Continues)

TABLE 3 (Continued)

General research aim[a]	Specific research objective[a]	Examples from previous research[a]	Qualitative method	Quantitative method
Critical reflection and reflexivity regarding the intervention	General experiences and narratives from all stakeholders		• CCI with clients and therapists • Post-Session Form for clients and therapists • Researchers' reflections	
	Co-development of intervention with all stakeholders ('co-researchers')			
	Critical self-reflection and reflexivity from the researcher		Researchers' reflections	
Feasibility of the research (e.g. study plan and organisational procedures)				
Exploration of general acceptance of the research	Explicit acceptance		CCI interviews with clients and therapists	
	Critical overall summary of all other objectives		Researchers' reflections	
Exploration of available resources for the research	General resources	Finances, rooms, staff, organisational skills, data collection and storage, research skills, team collaboration	• CCI with therapists and administrative staff • Researchers' reflections	
Exploration of research outcomes	Feasibility of recruitment and inclusion/exclusion criteria		• CCI with clients and therapists •Researchers' reflections	• Flowchart of inclusion and dropout rates at different stages • Sociodemographic variables of sample who finished all sessions and differences with dropouts
	Feasibility of instruments		• CCI with clients and therapists • Researchers' reflections	
	Feasibility of new questionnaires		• CCI with clients and therapists • Researchers' reflections	• Descriptive analyses, non-parametric associations and correlations of new questionnaires
	Feasibility of analysis			Explorative statistical analysis[a]
Exploration of the research processes	General experiences of the research process		CCI with clients and therapists	
Exploration of possible areas of improvement of research	Identify possible areas for improvement		• CCI with clients and therapists • Researchers' reflections	
Exploration of the sensitivity of research	Sensitivity of the research procedures to individual clients and context			Examination of dropout/attrition and missing values per client (non-parametric associations, correlations with sociodemographic variables)
	Sensitivity of the research procedures to individual researchers		CCI with therapists (e.g. evaluate learning needs, training and growth)	Examination of dropout/attrition and missing values per therapist

TABLE 3 (Continued)

General research aim[a]	Specific research objective[a]	Examples from previous research[a]	Qualitative method	Quantitative method
Critical reflection and reflexivity regarding the research procedures	General experiences and narratives from all stakeholders		• CCI with clients and therapists • Post-Session Form for clients and therapists • Researchers' reflections	
	Reliability of quantitative methods			Analysis of Cronbach's alpha and split-half reliability of all measures
	Validity of quantitative methods			Scatterplots, non-parametric associations and correlations between all measures
	Trustworthiness of qualitative methods		Researchers' reflections (e.g. regarding fidelity, utility, sensitivity to context, commitment and rigour, competencies and skills, coherence and transparency, impact and importance, credibility, dependability, transferability, confirmability, triangulation, authenticity; Vos, 2023)	
	Reflection on the causal relationships assumed in the study design		Researchers' reflections (e.g. strong association; consistency; specificity; logical timeline gradient; plausibility or coherence; experimental design; no alternative explanations; Vos, 2023)	

Note: CCI: Client Change Interview about: general experience, significant moments, positive, negative, lacking, expectancy, likelihood, importance, attribution of changes, helpful, unhelpful, potentially helpful aspects, missing aspects and research experiences; Post-Session Therapy Form about: general experience, topics discussed, significant moments, changes, helpful, unhelpful, potentially helpful aspects, missing aspects, recommendations; the therapists' form also asked about changes and deviations from the treatment manual or intervention guidance, and therapist's self-rating of the extent to which they skilfully used each of the key therapeutic competencies.

[a]Statistical analysis: descriptives (M, St. Dev., skew, kurtosis, outliers), description and analysis of missing data and outliers (do not impute missing values as this may bias the findings in such a small sample); consider repeated measures ANOVA, non-parametric tests, reliable clinical change (RCI) with known population RCI figures, meta-analysis comparison with benchmark groups.

mean scores seemed much reduced by one client with severe anxiety at therapy sessions one and two; when this client was deleted (as the primary focus of this treatment was treating depression and not anxiety), the statistical and clinical effect sizes were much larger (but she was kept in as such outliers may reflect clinical reality). The findings tentatively indicate that TAP may benefit clients similarly to other humanistic and relational therapies (Elliott, 2002; Vos et al., 2022).

4.1.2 | Processes

Both clients and therapists attributed the changes in the clients' lives to therapy, and they described a range of helpful factors after each session and also in the interviews, which seemed to confirm the therapeutic model that formed the foundations of the treatment manual (Vos, 2023). The session-by-session findings indicated gradual improvement in the primary outcome measures, with the largest change after the fourth and fifth sessions when the therapist shared the case formulation with the client (in the interviews, this was also often mentioned as an important moment in therapy).

4.1.3 | Sensitivity

Although all questionnaires showed variation, the findings were all in the same direction for the clients. There were no significant sociodemographic differences with the usual population in this clinic (Vos et al., 2022). The outcomes were not significantly correlated with any sociodemographic variables (although this may be due to the small sample size). This may be tentatively interpreted as the intervention being sensitive. There was an apparent learning effect in therapists'

competencies, which we had expected as this was the first TA clinical trial for the therapists.

4.1.4 | Improvement

Only minor areas for improvement were suggested (see Tables S1–S3).

4.1.5 | Resources

Reflections with the therapists and researchers suggested they had sufficient resources for the intervention.

4.1.6 | Acceptance

Overall, the TAP treatment manual seems acceptable, as the interviews with therapists and clients did not reveal any significant concerns, and the aforementioned research objectives appear to be satisfactorily achieved.

4.1.7 | Critical reflection

Overall, the intervention seemed feasible for a broad range of clients with depression, although it may be less beneficial for clients with mixed depression/anxiety when the anxiety seems to dominate. The intense focus on questionnaires may also not fit all clients and therapists, and the large learning curve of therapists may indicate that this manual may work better for experienced therapists. The study was limited by the small sample size, and the findings should be validated in studies with larger samples. These findings suggest that the TAP treatment manual is feasible and that a larger Phase 2 study is justified.

4.2 | Feasibility of TAP research procedures

The main aim of this study was to examine the feasibility of the intervention; therefore, we asked fewer questions to evaluate the research procedures. Overall, the findings suggested acceptance of this research project in this community clinic, based on the following. Evaluations with everyone involved in the project indicated that the clinic seemed to have sufficient resources for the study, with no significant problems. However, the start of inclusion was delayed due to staff changes. Of all eligible participants, 52.9% participated, without any dropouts, which seems acceptable given the extra time investment required to complete questionnaires compared with care as usual. The lack of significant sociodemographic differences with the average population (Vos et al., 2022) may be tentatively interpreted as the recruitment procedures being sensitive. Few participants completed the post-therapy questionnaires, and those that did said in the interview that they found the questionnaires long; this seems to suggest that future studies should include shorter questionnaires to prevent dropout and missing data. As all questionnaires seemed reliable and sensitive to detect changes in this population, it may be recommended to focus on questionnaires that are the closest to measuring the outcomes (depression/PHQ-9, life position/LPS, ego states/SMI and possibly the CORE10 or WHOQOL-BREF as generic questionnaires). As expected, all questionnaires seemed feasible in this study, with good reliability, variation and correlations. The case formulation forms did not include all relevant details and were not completed by all therapists; therefore, it may be appropriate to adjust or omit this. Obviously, the small sample size increased the likelihood of statistical bias. Consequently, the quantitative findings should be interpreted cautiously and confirmed in future larger samples. There are some indications of causality (i.e. TAP causing positive outcomes), thanks to the experimental design, logical timeline, coherent, positive effects, with changes specific to the treatment modality and confirmed by quantitative and qualitative methods. This study's strength lies in the triangulation and confirmation of information, transparency, systematic rigour and fitting to the context. It may be argued that a large amount of information could make the findings more difficult for readers to comprehend quickly. More information about how the research procedures may work in other samples and studies conducted by other researchers is needed.

4.3 | Feasibility of using mixed methods for feasibility studies

This study aimed to examine the feasibility of TAP and the feasibility of using mixed methods in feasibility research.

Quantitative and qualitative methods have been combined in some feasibility studies, but this study used a systematic mixed methods approach. The interviews and reflections with therapists, clients and researchers indicated that the mixed methods were generally accepted. In general, mixing methods seemed to give a rich account, offsetting the weaknesses and strengths against each other. Combining methods in the experimental study design seemed to enable stronger conclusions about the possible causality than with a single method. The quantitative methods gave an initial indication of positive effects and the absence of negative side effects. However, the quantitative methods were limited by the small sample size. The qualitative information added a more in-depth understanding of these generic quantitative findings, for example about the helpful and unhelpful factors and the broad range of subjective significance and attribution of changes in clients' lives.

However, the amount of requested information was large, which may have caused some clients not to complete the final questionnaires and one therapist not to provide the case formulations. Furthermore, giving a clear overview of the methods and findings in this article was challenging, as there was much to discuss. The relative information overload seemed to have been caused by our decision to use both a specific 'fishing rod' approach (e.g. interview questions and questionnaires specific to the treatment) as well as an explorative 'broad fishing net' approach (e.g. general interview questions and general quality-of-life questionnaires). Furthermore, it took more time to collect and analyse a large amount of

data, with potentially fewer individuals not completing the post-therapy questionnaire than if we had used only a smaller number of interview questions and questionnaires. It will depend on the available time of researchers and therapists whether they can do this in future. Therefore, it may be argued that, in principle, mixed methods may help in feasibility studies. Still, future researchers may want to cast their net more precisely than we did by being more selective in the questions, questionnaires and frequency of administering questionnaires.

Within these limitations, this study seems to indicate that using mixed methods is feasible. Based on experiences, Table 3 shows a protocol for developing and publishing feasibility studies in psychological therapies. However, more studies are needed to test this feasibility protocol in other populations. Finally, accepting this protocol for feasibility studies may only be ultimately proven by the responses from the reviewers, journal editors, readers and future researchers.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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