Common factors, Responsiveness and Outcome in Psychotherapy (CROP): study protocol for a naturalistic prospective cohort study of psychotherapy in Denmark

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STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ As a naturalistic cohort study, which utilises the natural variation in client, therapist and treatment characteristics to study the process and outcome of psychotherapy, the study has high ecological validity.
⇒ The study is practice oriented and builds on the principles of researcher–practitioner collaboration.
⇒ The study collects longitudinal process data through weekly and postsession questionnaires to study potential change mechanisms occurring in psychotherapy sessions and their temporal relationship.
⇒ Reflective of its naturalistic setting, the study lacks experimental control and accordingly no causal interpretations can be made from its results.

INTRODUCTION
Research shows that even though psychotherapy is generally effective,1 a substantial amount of patients do not achieve a satisfactory treatment outcome. Systematic reviews have found that full remission at the end of treatment was achieved by 48% of patients with anxiety2 and 43% of patients with depression.3 Even lower remission rates have been reported; for instance, in a large scale, high-quality Dutch trial comparing cognitive-behavioural and psychodynamic therapy for depression,4 only 22.7% of treatment completers were fully remitted. Accordingly, there is a need for identifying methods improving the outcome of psychotherapy.

A complicating factor is that although several psychotherapy methods are effective for specific disorders, differences in efficacy between well-established methods are typically negligible.5,6 This has led researchers to argue that psychotherapeutic outcome is largely predicted by treatment factors common to all psychotherapeutic approaches. A large body of research documents that positive qualities and skills of the therapist such as empathy with clients7 or ‘facilitative interpersonal skills’8 contribute to the establishment of a collaborative interpersonal relationship
between client and therapist and are associated with better outcome of therapy. On the other hand, even the common factor that has been subjected to most research, the therapeutic alliance, only accounts for relatively limited proportions of the outcome variance.

While the importance of the common factors is well documented, it has been harder to document the efficacy of specific therapeutic techniques, and studies attempting to establish causal links between such techniques and outcome have often found no or very modest associations (e.g. Ahn and Wampold, Bell et al and Longmore and Worrell10–12). However, recent studies using more sophisticated methods of analysis indicate that it is indeed possible to demonstrate causal relationships between theoryspecific elements of treatment and therapeutic outcome.13 Accordingly, both common and specific factors are likely to contribute to therapeutic outcome.

Furthermore, regardless of the specific approach, effective psychotherapy is characterised by adequate therapeutic responsiveness, that is, the therapists’ ability to adapt their approach to client characteristics and preferences.14–15 One overall approach to therapist responsiveness is to systematically choose different types of therapy for clients with different characteristics. This treatment paradigm, which is currently known as precision or personalised psychotherapy (Cohen and DeRubeis16) and corresponds to what has been designated aptitude–treatment interaction,17 has received increasing attention over the last decade. Research indicates that certain patient characteristics such as sociodemographic variables, comorbidity, treatment preferences and personality factors are systematically related to differential outcomes of various types of treatment.16–18–19 Furthermore, recent research suggests that personalised psychotherapy based on robust models of indicators for specific treatments may be within reach and has the potential to enhance the outcomes of psychotherapy.20

Responsiveness goes beyond the assignment of different treatment packages to clients with specific characteristics and may also be manifested by, for example, extending or abbreviating therapies according to the client’s needs and/or by continuously adapting techniques and interventions to the client throughout the psychotherapeutic process. Responsiveness may also refer to the way the therapist takes into account the interaction of common and specific factors during therapy, that is, that the impact of specific interventions is intrinsically related to the presence of common factors such as therapeutic alliance, therapist empathy, etc.22 While research has documented that therapist responsiveness is a ubiquitous phenomenon,14 the implications for outcome of therapist responsiveness during the therapeutic process are less well studied. Thus, even though a more general adaptation of therapy to the specific client seems warranted, this does not mean that responsiveness in clinical practice is always beneficial. Individual adaptation of the therapy to the client entails the risk of a less systematic approach, which may ultimately have a negative impact on outcome.

Overall, the existing evidence indicates that therapeutic improvement is facilitated through a complex interaction of common and specific factors and that therapists differ in their ability to implement such factors in a responsive manner that suits the individual client’s needs. Accordingly, there is a need for research investigating these interactions and therapists’ approaches to adaptation of therapy in naturalistic settings.

Aims

The present study focuses on psychotherapy conducted by psychologists who are either fully self-employed or employed in the Danish primary sector where clients are partly reimbursed. The study aims to use the natural variation in therapist, client and treatment characteristics found in psychotherapy conducted by psychologists in private practice to study the impact and interaction of a variety of possible determinants of the process and outcome of psychotherapy. A particular focus will be on the impact of therapist responsiveness. The naturalistic setting of the present study provides an ideal context for research into responsiveness, since a large variation in terms of clients’ mental states and conditions and of treatment approaches is expected. Furthermore, due to the relative freedom of choice of psychotherapeutic methods in the Danish primary sector, therapist responsiveness is not constrained by a treatment manual.

The main research questions of the study are:

► Is psychotherapy provided in the Danish primary sector or in non-reimbursed private practice associated with significant improvement in psychiatric symptoms?

► Is outcome of psychotherapy and client dropout predicted or moderated by psychotherapeutic approach, sociodemographic variables, client personality characteristics, psychologist professional and personality characteristics, and/or client therapy preferences?

► Is the overall flexibility of the psychologists’ therapeutic approach associated with treatment outcome and/or the alliance?

► Is the formation of an attachment-like relationship between clients and therapists associated with better therapy outcome?

► Can we identify clusters of patients with distinctively different patterns of symptom change over the course of psychotherapy and which baseline variables predict such patterns?

Please see online supplemental appendix I for a detailed presentation of the individual substudies, including research questions, hypotheses and study variables.

METHODS AND ANALYSIS

Study design and procedures

The CROP study is a naturalistic prospective cohort study of therapy outcomes and processes carried out by psychologists in private practice. Self-report data are collected from psychologists and their clients through
an automated and secure online database. Background data from the psychologists and clients are collected before the first therapy session, and process and outcome data are collected from both client and psychologist throughout each therapy course with predefined intervals. At the end of therapy, data are collected from the clients and therapists, and at 3 months follow-up, data are collected from the clients.

All questionnaires are filled in online with links provided through emails to psychologists and through emails or text messages to clients. Reminders are sent automatically in case of no response. Every time a new client has agreed to participate in the study, the psychologist will register the specific client in the system using an anonymous ID and the client will receive an informed consent form to be signed digitally. When the consent form is signed, the client will automatically receive links to the relevant questionnaires. Throughout the therapy course, the clients receive weekly symptom questionnaires and both clients and psychologists receive process questionnaires after every session in a regular pattern where each questionnaire is repeated every third session. When the psychologist registers that the therapy has ended, and at 3 months follow-up, the client will receive the outcome questionnaires. Data are delivered to the research team in a fully anonymised format.

Prior to the implementation of the current design, a pilot study comprising 10 psychologists with one or two clients each was conducted in August 2018. We found that the automatic data collection procedure is working reliably and constitutes a feasible approach to data collection. Data collection for the proper study was initiated in January 2019 and is expected to continue until the end of 2023 pending on the attainment of the target sample size of 573 clients.

Participants
Psychologists
All psychologists with a Danish university degree in psychology who have registered themselves as seeing clients in private practice (approximately 1800) have been invited to participate in the study. Thus, the sample of psychologists consists of psychologists employed in the Danish primary sector, where clients with a referral from their general practitioner obtain a 60% refund of their expenses for psychotherapy as well as psychologists working privately without any reimbursement of their salaries. Each psychologist enrolled in the study has agreed to aim to recruit no fewer than 10 clients each for the study. We aim to include 60 psychologists, which will yield a sample of 600 clients beginning therapy. Psychologists are instructed to include three clients initially and subsequently include a new client whenever ending therapy with a client enrolled in the study. A minimum of 10 clients per therapist increase the possibility of estimating the effect of the therapists in a multilevel model analysis, while asking the therapists to limit the number of concurrent clients helps prevent exhaustion with the study and possible attrition.

Recruitment of psychologists will take place through newsletters and e-mails sent to relevant professional societies. Furthermore, the study will be announced at professional meetings as well as on social media platforms for psychologists in private practice. To motivate psychologists to participate in the study, the psychologists will receive 1000 Danish kroner (~ 135 Euros) per client enrolled in the study. This sum is roughly equivalent to the average salary per hour for a psychologist in private practice and will to some extent compensate the psychologist for the time dedicated to the study. Furthermore, psychologists will be invited to participate in online lectures and seminars focusing on the implications of psychotherapy research for clinical practice and on the findings of the present study.

Clients
All clients in individual psychotherapy aged 18 or older are eligible for the study, meaning that in principle all client diagnoses and referral reasons may be represented in the sample. However, in Denmark, reimbursement for psychological treatment in the primary sector is only provided for clients referred by their general practitioner for 1 of the 11 referral reasons and diagnoses presented below. Thus, clients meeting these characteristics are likely to be over-represented within the sample:

► Victims of robbery, violence and rape
► Victims of traffic and other accidents
► Relatives of seriously mentally ill persons
► Persons suffering from a seriously debilitating illness
► Relatives of persons suffering from a seriously debilitating illness
► Relatives of recently deceased persons
► Persons who have attempted suicide
► Women having undergone an induced abortion after the 12th week of pregnancy
► Persons who, before the age of 18, have been victims of incest or other sexual assaults
► Persons aged 18 or above with mild to moderate depression
► Persons aged 18 or above with mild to moderate anxiety disorder, including mild to moderate OCD.

Treatments within the Danish primary sector are in principle limited to 12 sessions. However, the general practitioner is allowed to refer clients diagnosed with depression or anxiety to up to 12 more sessions if necessary. Since the study also includes open-ended treatments fully funded by the clients, all treatment lengths will be included in the study.

Measures
All measures listed have been back translated and approved by the original authors unless otherwise noted. See table 1 for an overview of all measures and the time points where they are presented to the participants.
### Table 1 Study measures

<table>
<thead>
<tr>
<th>Time</th>
<th>Psychologist</th>
<th>Client</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before enrolling first client</td>
<td>DPCCQ, ECR, SASB, ProQOL, IIP, RFQ</td>
<td></td>
</tr>
<tr>
<td>First session</td>
<td></td>
<td></td>
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<tr>
<td>Before session</td>
<td></td>
<td></td>
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<tr>
<td>Post-session</td>
<td></td>
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<tr>
<td>Weekly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>End of treatment</td>
<td>CSQ, TC, BSI, WHO-5, LPFS-BF, IIP, ECR, RFQ</td>
<td>PG-13</td>
</tr>
<tr>
<td>Three months follow-up</td>
<td>TC, BSI, WHO-5, LPFS-BF, IIP, ECR, RFQ + (if relevant) PG-13</td>
<td>PG-13</td>
</tr>
</tbody>
</table>

### Table 1 Continued

<table>
<thead>
<tr>
<th>Time</th>
<th>Psychologist</th>
<th>Client</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSI, Brief Symptom Inventory; CATS, Client Satisfaction to Therapist Scale; CSQ, Client Satisfaction Questionnaire; DPCCQ, Development of Psychotherapist Common Core Questionnaire; ECR, Experiences in Close Relationships; FWC-10, Feeling Word Checklist; IIP, Inventory of Interpersonal Problems; LPFS-BF, Level of Personality Functioning Scale—Brief Form; PEX-P1, Psychotherapy Preferences and Experiences; PEX-T1, therapist version of the PEX; PG-13, Prolonged Grief Disorder Scale; ProQOL, Professional Quality of Life Scale; RAPIDPractice, Retrospective Analysis of Psychotherapists’ Involvement in Deliberate Practice; RFQ, Reflective Function Questionnaire; SAI, Session Alliance Inventory; SASB, Structural Analysis of Social Behavior Introject Surface; SCL-11, Symptom Checklist-11; TC, Target Complaints; TDS, The Therapeutic Distance Scale; TFS, Therapist Feedback and Reflection Scale; TFS, Therapist Flexibility Scale; URICA-S, University of Rhode Island Change Assessment Scale—Short Version; WAI-S, Working Alliance Inventory-Short Form; WHO-5, The World Health Organisation-Five Well-Being Index.</td>
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**Psychologist characteristics**

When entering the study, therapists will provide information using the following questionnaires:

*Development of Psychotherapist Common Core Questionnaire (DPCCQ)* measures the personal and professional characteristics and experiences of psychotherapists and their retrospectively and currently experienced development. Most of the items are designed in a 4-point or 6-point Likert-type format. The scales are internally consistent and adequately differentiated and a degree of construct validity has also been demonstrated. The present study uses an abbreviated version consisting of 138 items.

*Experiences in Close Relationships- Revised (ECR-R)* is a questionnaire containing 36 items that measure two kinds of attachment insecurity: Attachment avoidance, characterised by fear of interpersonal dependence and intimacy, and Attachment anxiety, characterised by fear of abandonment and craving for interpersonal closeness. The measure has displayed a clear two-factor structure and provides reliable and replicable measures of both the attachment anxiety and avoidance subscales. The approved Danish translation of the measure has been revised to focus on close relationships in general rather than on a romantic partner.

*The Structural Analysis of Social Behavior Introject Surface, Intrex (SASB-IS)* is a questionnaire focusing on the individual’s way of relating to the self, measured across two dimensions: Autonomy (from self-freeing to self-controlling) and Affiliation (from friendly to hostile). The short eight-item form is used. Each item is rated two times, representing both the individual’s best and worst states. The measure has shown good concurrent and predictive validity as well as strong test–retest reliability in normal and clinical samples.

*The Professional Quality of Life scale (ProQOL)* is a 30-item questionnaire measuring compassion satisfaction and compassion fatigue. Compassion fatigue consists of...
two subscales, one concerning feelings of burnout and one assessing secondary traumatic stress through work-related trauma. The scale has shown good to strong internal reliability and good construct, discriminant and convergent validity.

*Inventory of Interpersonal Problems (IIP-32)* measures difficulties that people experience in their interpersonal relationships, experienced as things people find *too hard* to do or things they do *too much*. The IIP has eight subscales: hard to be sociable, hard to be assertive, too aggressive, too open, too caring, hard to be supportive, hard to be involved and too dependent. The abbreviated, 32-item version of the IIP is used, which has shown very good internal consistency and functions comparably to the original 127-item IIP.

*Reflective Function Questionnaire (RFQ)* measures mentalisation, that is, the capacity to understand both the self and others in terms of internal mental states. The RFQ has two subscales, measuring *certainty* and *uncertainty* about the mental states of self and others. The measure has shown a distinct and invariant two-factor structure and satisfactory internal consistency and test–retest stability.

In the present study, the eight-item version of the scale is used.

**Client characteristics**

Before the first session with the therapist, clients will receive the following questionnaires:

*Demographic information*. This questionnaire consists of 12 items regarding the clients’ gender, age, employment status, education, marital status, children, alcohol consumption and drug use, former mental health problems and current and previous treatment and experiences of any potentially traumatic events.

*Target complaints* (TC) is an individualised measure of psychotherapy outcome, where clients give a qualitative description of their three most important complaints and rate the severity of each on a scale from 1 (‘not at all’) to 12 (‘can’t get worse’). Strong concurrent validity has been demonstrated for the measure with target complaints ratings significantly correlating with anxiety measures, psychological distress, symptom severity and client satisfaction.

*Brief Symptom Inventory (BSI)* is a self-report scale consisting of 53 items covering nine symptom dimensions: Somatisation, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation and Psychoticism. The symptom dimensions and the global scale (the Global Severity Index) of the BSI have shown acceptable to excellent internal consistency and test–retest reliability. Good convergent and construct validity have also been demonstrated.

*SCOFF* is a five-item screening tool addressing core features of anorexia nervosa and bulimia nervosa and designed to clarify suspicion that an eating disorder might exist. An answer of ‘yes’ to two or more questions warrants a more comprehensive assessment. In the present study, the items were presented to the participants in a questionnaire format. A meta-analysis of the diagnostic accuracy of SCOFF show high specificity and sensitivity estimates for the measure.

*The World Health Organisation- Five Well-Being Index (WHO-5)* is a global rating scale that measures subjective psychological well-being. The respondent is asked to rate five positively phrased statements and consider how well they apply when considering the last 14 days. In studies of younger and elderly persons, the WHO-5 has shown good construct validity as a unidimensional scale measuring well-being in these populations.

*Level of Personality Functioning Scale—Brief Form 2.0 (LPFS-BF)* is a 12-item questionnaire developed to assess levels of personality functioning. The items are clustered into four subscales, *Empathy, Intimacy, Self-Direction and Identity*, which are clustered into two higher domains, *Self-Functioning* and *Interpersonal Functioning*. A study utilising the Danish version of the measure has demonstrated satisfactory internal consistency, a confirmation of the two-factor self–other structure, and promising criterion validity.

*University of Rhode Island Change Assessment Scale—Short Version (URICA-S)* is a 16-item self-report measure based on the trans-theoretical model of change and consisting of four subscales measuring the stages of change: *Precontemplation, Contemplation, Action* and *Maintenance*. The measure shows poor to good internal consistency with high correlations to the long version of the scale. Criterion validity has been demonstrated via significant outcome predictions by contemplation, action and maintenance.

*Psychotherapy Preferences and Experiences (PEX)* is a self-report measure designed to be used at various stages of therapy. In the client version of the PEX applied prior to therapy (PEX-P1), the clients are asked to rate the extent to which they believe they would be helped by specific therapeutic interventions and therapist techniques. The version of PEX used in the present study consists of 25 items grouped in five subscales: *Inward Orientation* (interventions focusing on exploration of inner mental processes), *Outward Orientation* (focusing on concrete and directive problem solving), *Affect Expression* (focusing on expression of affect), *Affect Suppression* (focusing on emotional control and avoidance of psychological discomfort) and *Support* (focusing on active advice, encouragement and sympathy from the therapist). Psychometric properties are satisfactory and the scale has shown high internal consistency.

In addition to these questionnaires, all clients also fill in IIP-32, ECR and RFQ-8 (see *Psychologist characteristics* above).

Clients whose reason for referral is bereavement will also receive the *Prolonged Grief Disorder scale (PG-13)*, a 13-item self-report measure designed to assess poor adjustment to bereavement 6 months post-death and beyond. The PG-13 has shown high internal consistency and good concurrent validity in a sample of bereaved parents.
Weekly outcome measures
Starting after the first therapy session, clients will receive the following questionnaire every week:

Symptom Checklist-11 (SCL-11[2]) is a short, multidimensional outcome measure for the evaluation of psychotherapeutic progress, consisting of 11 items selected from the BSI using a stepwise item-selection procedure where items were selected according to content validity (depression and anxiety diagnostic criteria), convergent validity (correlation with BDI and SCL-90-R), test–retest reliability and change sensitivity.[3]

Session measures
After each session, clients and therapists fill in a brief alliance inventory along with a supplementary questionnaire. To keep the number of questions after each session to a minimum, the supplementary questionnaire will alternate from session to session, with each questionnaire being repeated every third session (cf. table 1 for details). The specific questionnaires are the following:

Therapists
PEX-T1[4] is the 25-item therapist version of the PEX-scale for use before beginning therapy. In the present study, the questionnaire is filled in by the psychologist after the first session with a specific client. In the PEX-T1, the therapist is asked to rate the extent to which they believe their client would be helped by each of the therapeutic interventions and therapist characteristics listed in all versions of the PEX.

Working Alliance Inventory-Short Form (WAI-S)[5] is a 12-item, self-report measure assessing agreement on the tasks and goals of therapy and development of a positive affective bond between the therapist and the client. The psychometric properties of the short-form measure are reasonably good with especially the total alliance score showing excellent internal consistency.[6] In the present study, one item is added to ensure overlap of items with the Session Alliance Inventory presented to the client.[7] The WAI-S is rated by the therapist after each session.

Therapist Feedback and Reflection Scale (TFRS) is an 11-item questionnaire developed for the present study. The therapist is asked to rate the extent to which he/she has received feedback from the client during the session and whether he/she has been surprised by anything in the session or felt in doubt about the therapeutic approach.

Feeling Word Checklist (FWC-BV)[8] is a 12-item version of a questionnaire used to assess to what degree the therapist has experienced various feelings when interacting with the client in the psychotherapy session. The FWC-BV has shown adequate psychometric properties in a large-scale study of outpatients. In the present study, the 10 items included in the three-factor model found by Breivik and colleagues were used, with two additional items (‘confident’ and ‘indifferent’) added to the measure.

Retrospective Analysis of Psychotherapists’ Involvement in Deliberate Practice (RAPIDPractice)[9] is a survey instrument where respondents are asked to rate the frequency with which they have engaged in a number of activities aimed at improving therapeutic skills. An abbreviated, 11-item version was used in the present study.

Therapist Flexibility Scale is a four-item questionnaire developed for this study, focusing on whether the therapist had changed his/her therapeutic approach, focus or understanding prior to or in the latest session with the client.

PEX-T2[10] is the 25-item therapist version of the PEX for use after therapy sessions. The therapist is asked to rate to which extent his/her work with the client was characterised each of the therapeutic interventions and techniques listed in all versions of the PEX.

Clients
Session Alliance Inventory (SAI)[11] is a six-item, client version of the WAI, developed specifically to measure the working alliance repeatedly across sessions of psychotherapy. The total composite score of the SAI shows excellent internal reliability.[12] In the present study, the client fills in the SAI after each session.

The Therapeutic Distance Scale (TDS)[13] is a self-report measure developed to assess clients’ experiences of distance versus engagement with their therapist. An abbreviated, 18-item version was used for the present study, consisting of four subscales: Too Close (the client perceiving the therapist as intrusive), Too Distant (the client perceiving the therapist as distant or rejecting), Growing Engagement (the client perceiving a decreased anxiety in sessions) and Growing Autonomy (the client perceiving an increase in agency). In a student sample, the internal and test–retest reliability of the full-version measure was acceptable. In addition, correlations of TDS subscales with WAI total scores and Client Attachment to Therapist Scale (CATS) subscales were significant and in expected directions.[14]

The Client Attachment to Therapist Scale (CATS)[15] is a self-report measure developed to assess the client–therapist relationship from the perspective of attachment theory. The version used in the present study consists of 18 items and three subscales: Secure, Avoidant-Fearful and Preoccupied-Merger. The secure subscale rates the extent to which the client experiences the therapist as, for example, responsive, sensitive and understanding. The avoidant-fearful subscale assesses, for example, suspicion that the therapist is disapproving, dishonest or likely to be rejecting. The preoccupied-merger subscale rates a longing for more contact beyond the bounds of therapy and to be ‘at one’ with the therapist. Acceptable internal consistency and test–retest reliability coefficients have been found for the subscales in the full-version measure.

PEX-P2[16] is the client version of the PEX-scale for use after therapy sessions. In the present study, the client is asked to rate the extent to which the therapist made use of each of the therapeutic interventions or techniques listed in all versions of the PEX.
End-of-treatment measures

At the end of the treatment, therapists fill in items concerning the client’s diagnosis and the therapeutic approach used during the treatment course. Clients rate the baseline measures relevant for treatment outcome, that is, _TC_, _BSI_, _WHO-5_, _LPFS_, _HIP_, _ECR_, _RFQ_ and (if relevant) _PG-I_. Furthermore, clients fill in the following questionnaire:

The Client Satisfaction Questionnaire (CSQ-8)\(^{53}\) is an eight-item form concerning the client’s overall satisfaction with their psychotherapy treatment. The CSQ-8 shows excellent internal consistency and is widely used in mental health service settings.\(^{54}\)

Follow-up measures

Three months after treatment completion, the clients will fill in all end-of-treatment measures again, except the CSQ.

Patient and public involvement

The participating psychologists have continuously provided feedback on the design and procedures of the study. Furthermore, five clients were interviewed about their experience of participating in the study. The interviews were analysed using thematic analysis.\(^{55}\) The overall findings were that the clients were motivated by experiencing that their participation contributed to the improvement of the practice of psychotherapy and that filling in the questionnaires contributed to their reflections on their current state.

Statistical analyses

The primary statistical analyses will consist of multilevel growth curve models, in which predictors and moderators of the level and rate of change in therapy outcomes are tested over time, or structural equation modelling (SEM) approaches to investigate change during the psychotherapy process. In substudy A, we study the outcome of psychotherapy, testing various shapes of change in a preliminary step and subsequently investigating how client variables (eg, therapeutic preferences or personality pathology) interact with therapist variables (eg, therapeutic approach) in predicting therapy outcome (eg, dropout and symptom change). In substudy B, we investigate session-to-session changes in the client’s treatment preferences and the therapist’s treatment approach using panel data modelling in the SEM framework. In substudy C, we explore client attachment variables in the therapy process, for example, the interaction between pretreatment attachment style, the client-therapist attachment relationship and the outcome of therapy. Detailed descriptions of these and other substudies, including statistical analyses and research aims, are found in online supplemental appendix 1.

Due to the complexity of power analysis for multilevel models, we used a simplified power analysis based on multiple regression. The overall sample size of the study was set to obtain sufficient statistical power to detect small effect sizes in multiple regression analyses. Sample size was calculated in G*Power V.3.1. To detect what has been designated by Cohen\(^ {56} \) as a small effect size ($\hat{f}^2=0.02$) of the predictor variables, with a power of 90% and an $\alpha$-level of 5%, 430 participants are needed. Allowing for a dropout rate of 25%, the sample size needed for the study is 573 participants. Missing data will be dealt with using multiple imputation\(^ {57}\) based on all available client and therapist measures.

Ethics and dissemination

All data are fully anonymised and stored in agreement with the Danish Act on Processing of Personal Data. All parts of the study are based on the principles of informed consent and clients are informed that they can terminate their participation in the study at any time without consequences to their treatment. The study design and data management procedure have been approved by the Ethical Review Board at the Department of Psychology, University of Copenhagen (IRB number: IP-IRB/01082018) and the Danish Data Protection Agency. The findings of the study will be presented in articles in international, peer-reviewed journals as well as to psychotherapy practitioners and other professionals across Denmark.

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Contributors

The study was designed by SP, LRL, JN, SL and BBM. This protocol was primarily formulated by LRL. SP and CFJ. FF provided statistical advice and all authors revised and approved the final version of the manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

Data availability statement

Once the results of the study have been published, anonymised datasets can be provided upon request.

Supplemental material

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REFERENCES


Appendix 1: Specific substudies

Substudy A: Client, psychologist and treatment characteristics related to the outcome of psychotherapy in private practice.

The aim of this study is to provide information about the outcome of psychotherapies conducted in the Danish Primary Sector or by psychologists in non-reimbursed private practice in Denmark. In addition, we aim to investigate possible specific effects of specific treatment approaches and to identify client and psychologist characteristics predicting and/or moderating the outcome of various psychotherapeutic approaches as they are delivered by practicing psychologists. We expect to report the results of the study in a series of articles, focusing on client treatment preferences and therapist treatment approaches, client psychological characteristics, and psychologist characteristics respectively.

Through longitudinal multilevel modeling (1), with measurement points nested within clients and clients nested within therapists, we will evaluate the extent to which the psychotherapies are associated with statistically significant symptomatic improvement, using the Symptom Checklist-11 (SCL-11) as main outcome measure. We will additionally report the proportion of clients with clinically reliable change as measured by the Reliable Change Index (2) and the proportion of clients reported as dropped out from therapy. Furthermore, we will investigate whether client characteristics such as socio-demographic variables, attachment patterns or personality disorder pathology and/or psychologist characteristics such as attachment patterns or self-concept serve as general predictors of treatment outcome. Additionally, we aim to examine whether the therapist’s psychotherapeutic approach (measured by PEX-T1), the client’s psychotherapeutic preferences (measured by PEX-P1), and the degree of match between the therapist’s approach and the client’s preferences (measured as the difference value between the PEX-P1 and the PEX-T1) serve as predictors of symptom improvement and treatment dropout. Finally, we aim to explore whether the client’s attachment pattern or personality disorder pathology, along with their psychotherapy treatment preferences, moderate the outcome of various psychotherapeutic approaches.

We expect to find statistically significant symptomatic improvements with medium to high within-group effect sizes within the client sample. Furthermore, we hypothesize to find a matching effect between the therapists’ therapeutic approach and the clients’ treatment preferences, in that a higher
degree of match between the two (and thus a smaller difference value) will predict better outcomes (3). We do not, however, expect to find a significant effect of the psychologists’ psychotherapeutic approach as a general predictor of outcome.

Furthermore, we hypothesize that clients’ scores on the attachment anxiety and attachment avoidance scales on the Experiences in Close Relationships Scale (ECR), and the total score on the Level of Personality Functioning Scale (LPFS) will significantly predict treatment outcome (3). In addition, we investigate whether these variables moderate the outcome of various treatment approaches. Specifically, we aim to explore whether attachment anxiety are associated with better outcome in therapies high on the PEX subscales inward orientation and affect expression, whether higher scores on attachment avoidance is associated with better outcome in therapies high on outward orientation, and whether higher scores on attachment anxiety is associated with better outcome in therapies high on support (4). Finally, we want to explore whether psychologists’ scores on the ECR-scales and the Structural Analysis of Social Behavior Introject Surface, Intrex (SASB-IS) are associated with treatment outcome.

Substudy B: The client preference-therapist approach relationship and its association with psychotherapy process and outcome.

Using panel data modeling within the structural equation modeling (SEM) framework (5), this study aims to investigate 1) whether the psychologists’ adaptation of their interventions to the clients’ treatment preferences is associated with treatment outcome and/or the therapeutic alliance, and 2) to what extent the flexibility of the psychologists’ therapeutic approach, both across clients and within a course of therapy, is associated with treatment outcome and/or the alliance.

To answer our first question, we will calculate the aggregated difference score between client preferences measured at baseline on the five PEX subscales and repeated measures of the client’s experiences of the therapist’s interventions measured on the corresponding PEX subscales. We will subsequently investigate whether the degree of match between preferences and therapeutic approach at various time points is associated with client rated alliance measured by SAI and/or outcome measured by the SCL-11. To answer our second question, we will investigate whether a) within-therapist variation on the PEX subscales across different clients and/or b) therapist within-client variation on the PEX subscales is associated with therapy outcome measured by the SCL-11.
Since the study focuses on within-client variation, only cases with at least two completed forms of PEX-T2 will be included.

We hypothesize that a greater match between the client’s preferences and the therapist’s approach through up to 12 sessions of therapy (corresponding to a conventional Danish psychotherapy course) will be associated with better client ratings of alliance on the SAI and/or better treatment outcomes on the SCL-11. We further hypothesize that greater within-therapist variation in therapeutic techniques will be associated with better outcomes, that is, therapists who respond in more individualized ways to different clients will achieve better results. For within-client variation in therapist interventions, we expect to find a curvilinear relationship with alliance and outcome. This is because low variation suggests rigidity and lack of adjustment of the therapeutic method to the current state of the client, whereas high variation suggests too much oscillation in strategies, which is likely to confuse and frustrate clients.

Substudy C: Client-therapist attachment, therapeutic distance, and its relationship with psychotherapy process and outcome.

The aim of this study is to identify factors related to the formation of an attachment-like relationship between clients and therapists (measured by the CATS) and to investigate whether the strength of this attachment relationship is associated with the process and outcome of therapy. Further, the study seeks to clarify whether the client’s perception of changes in engagement or autonomy during therapy (measured by the TDS) based on their particular form of attachment insecurity (measured by the ECR) is associated with therapy outcome (measured by the IIP-32). Since the study focuses on the development in the relationship measured by CATS and TDS, only cases with at least two completed forms of each measure will be included.

We hypothesize 1) that the formation of an attachment-like relationship is generally beneficial for clients, and 2) that the attachment relationship is associated with multiple factors, including length of treatment, the client’s pretreatment attachment pattern, and the client’s experience of growing engagement or growing autonomy in therapy. Regarding the client’s perception of therapeutic distance, we hypothesize 3) that for clients high on attachment avoidance, the most helpful therapies will be characterized by growing engagement on the TDS, whereas for clients high on attachment anxiety, the most helpful therapies will be characterized by growing autonomy on the TDS (6).
Based on the repeated measurements of the data and the focus of the study on between-person differences in the therapy process, our overall statistical approach will be multilevel modeling (1).

**Substudy D: Different outcome trajectories and predictors of these trajectories**

This study aims to investigate whether clusters of patients with distinctively different outcome trajectories, i.e., distinct patterns of change in the SCL-11 over the course of psychotherapy, can be identified in the client sample. The second aim of the study is to search for possible predictors of such trajectories.

Through growth mixture modeling (7), the study will investigate trajectories in the subsample of clients in treatment for anxiety or depression in the primary sector. The clients treated for anxiety or depression are specifically comparable by having a diagnosis with symptoms of negative affectivity (8) and by receiving similar numbers of sessions (12 session with a possible extension of another 12 sessions). Through chi-square tests, we will investigate whether individuals in various growth classes have varying odds of different sociodemographic characteristics such as employment and cohabitation status. Furthermore, through multilevel multinomial logistic regression, we will investigate whether client baseline characteristics such as their symptom severity (measured by the BSI) and personality characteristics including interpersonal problems (measured by the IIP-32), attachment patterns (measured by the ECR) and personality functioning (measured by the LPFS-BF) predict growth classes.

**Substudy E: The process characteristics and trajectories of negative therapy outcomes**

This study focuses on the therapy process of specific classes of clients who either exhibit no treatment response or negative psychotherapy outcomes such as premature termination (dropout) or clinically significant deterioration as measured by the Reliable Change Index (2). The aim of the study is to investigate whether specific client process characteristics, for instance changes in the client-rated working alliance (measured through the SAI), frequency of client-rated alliance ruptures or distinct symptomatic changes on the SCL-11, predict no or negative treatment outcomes.
As process-outcome research on negative therapy outcomes is scarce, the study will have no \textit{a priori} hypotheses about what client and therapist process variables may predict no or negative treatment response. Considering the focus of the study on dynamic associations between process variables in longitudinal data, the general statistical approach will be Structural Equation Modeling (5).

References:


