

TA Treatment of Depression: A Hermeneutic Single-Case Efficacy Design Study – Beatrice

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Abstract

This study is the sixth of a series of seven and belongs to the second Italian systematic replication of findings from previous series that investigated the effectiveness of a manualized transactional analysis treatment for depression through Hermeneutic Single-Case Efficacy Design. The therapist was a white Italian woman with 10 years of clinical experience and the client, Beatrice, was a 45-year old white Italian woman who attended sixteen sessions of transactional analysis psychotherapy. Beatrice satisfied DSM 5 criteria for Major Depressive Disorder, Anxious Distress, with Dependent and Histrionic Personality Traits. The judges evaluated the case as a good outcome: the depressive and anxious symptomatology clinically and reliably improved over the course of the therapy and these improvements were maintained throughout the duration of the follow up intervals. Furthermore, the client reported significant change in her post-treatment interview and these changes were directly attributed to the therapy.

Key words

Systematic Case Study Research; Hermeneutic Single-Case Efficacy Design; Transactional Analysis Psychotherapy; Major Depressive Disorder; Anxious Distress; Dependent Personality Traits; Histrionic Personality Traits.

Introduction

This Hermeneutic Single-Case Efficacy Design (HSCED) is the sixth of a series of seven, and belongs to an Italian systematic replication of findings from previous case series (Widdowson 2012a, 2012b, 2012c, 2013, 2014; Benelli, 2016a, 2016b, 2016c, 2017a, 2017b, 2017c) and is conducted under the auspices of the project 'Transactional Analysis meets Academic Research in order to become an Empirically Supported Treatment: an Italian two-year plan for

publishing evidence of Transactional Analysis efficacy and effectiveness into worldwide recognized scientific journals', funded by the European Association for Transactional Analysis (EATA).

Previous publications have widely described the rationale for supporting by HSCED the accumulation of evidences of efficacy and effectiveness for those models of psychotherapy that are emerging or marginalized (Benelli, De Carlo, Biffi & McLeod, 2015) and specifically how this is important for recognition of TA and inclusion within the acknowledged treatments for common mental disorders (i.e., depression, anxiety and personality disorders) (Widdowson 2012a, 2012b, 2012c, 2013, 2014; Benelli, 2016a, 2016b, 2016c, 2017a, 2017b, 2017c).

The aim of this study was to investigate the effectiveness of the manualised TA treatment of depression (Widdowson, 2016) applied to a major depressive disorder in comorbidity with anxious distress. The quantitative primary outcomes investigated were depressive and anxious symptomatology, the secondary outcomes were global distress and client-generated personal problems, which were analysed both quantitatively and qualitatively.

The present study analyses the treatment of 'Beatrice', a 45-year-old Italian woman with diagnosis of major depressive disorder in comorbidity with anxious distress, dependent and histrionic personality disorder.

Ethical Considerations

The research protocol follows the requirements of the ethical code for Research in Psychotherapy of the Italian Association of Psychology, and the American Psychological Association guidelines on the rights and confidentiality of research participants. The research protocol has been approved by the Ethical Committee

of the University of Padua. Before entering the treatment, clients received an information pack, including a detailed description of the research protocol, and they gave a signed informed consent and written permission to include segments of disguised transcripts of sessions or interviews within scientific articles or conference presentations. Patients were informed that they would have received therapy even if they decided not to participate in the research and that they were able to withdraw from the study at any point, without any negative impact on their therapy. All aspects of the case material were disguised, so that neither the client nor third parties are identifiable. All changes are made in such a way that does not lead the reader to draw false conclusions related to the described clinical phenomena. Finally, as a member checking procedure (Lincoln & Guba 1985), that is a qualitative research technique wherein the researcher compares her understanding of what an interview participant said or meant with the participant to ensure that the researcher's interpretation is accurate, the final article in English language was presented to the client, who read the manuscript, amended it, and confirmed that it was a true and accurate record of the therapy and gave her final written consent for its publication.

Methodology

Inclusion and exclusion criteria

Psychotherapists participating in this case series were invited to include in their studies the first new client with a disorder within the depressive spectrum as described in DSM-5 (Major, Persistent or Other Depressive Disorders) (APA, 2013) who agreed to participate in the research. Other current psychotherapy, active psychosis, domestic violence, bipolar disorder, active current use of antidepressant medication, alcohol or drug abuse were all considered as exclusion criteria. As the overall aim of this project is to study the effectiveness of TA psychotherapy in routine clinical practice, comorbidity is normally accepted and both inclusion and exclusion criteria are evaluated on a case by case.

Client

Beatrice is a 45 year-old white Italian woman who lives in a large metropolitan area in Italy. At the beginning of therapy she was living with her partner of five years, with whom she was trying to have a baby before finding out that she was not able to have biological children after many In Vitro Fertilizations (IVFs). Her relationship with this man was contaminated by his taking care (economically and emotionally) of the sister of his dead ex-girlfriend, who lived next door. Between sessions 3 and 4 Beatrice met another man with whom she fell rapidly in love and left her partner, but only between session 10 and 11 did she move into a new house by herself, even though her new partner slept in her house every night. Her new and actual

partner had a child from a previous relationship, who lived in a city far away from the father, who visited one or two weekends each month. Beatrice had never been single since she was 18 years old, and every relationship ended because she noticed the many problematic aspects of the current relationship and consequentially fell in love with somebody else. She had the tendency to lie to her current partner about her needs and feelings because she feared these would have made him break up with her and leave her alone, until she found a new man interested in her. Beatrice believed that she was only capable of making people she loved suffer. Nevertheless, she had many and very different long-lasting relationships. When she was younger she got pregnant by the then current partner but decided to abort because she did not love him anymore and because she was studying at university. She is a very intelligent and intuitive woman, she reported to be very good in her job and to like it, even though she felt embarrassed when she had to talk in front of her colleagues. She loves her parents but she had always felt to have been unwanted by them, especially by her mother. Her mother became pregnant with her when she was breastfeeding her first son, had at a very young age one year earlier. She loves her brother too, but she had always felt to be failing compared to him, even if he flunked at high school and she had always got the highest scores. She decided to start therapy after being addressed by her gynaecologist for her impossibility of having biological children.

Therapist

The psychotherapist is a 40 year-old, white, Italian woman with 10 years of clinical experience and who has a certification as Provisional Teaching & Supervising Transactional Analyst (Psychotherapy) (PTSTA-P). For this case, she received weekly supervision by a Teaching & Supervising Transactional Analyst (Psychotherapy) (TSTA-P) with 15 years of experience.

Intake sessions

The client attended three pre-treatment sessions (0A, 0B, 0C), which were focused on explaining the research project, obtaining consent, conducting a diagnostic evaluation according to DSM-5 criteria (American Psychiatric Association, 2013) and the TA model, developing a case formulation and a treatment plan, defining the problems she was seeking help for in therapy, as well as their duration and their severity (i.e., preparing the Personal Questionnaire, see later), and collecting a stable baseline of self-reported measure for primary (depression and anxiety) and secondary (global distress, personal problems) outcomes. In intake sessions she described as major symptoms: loss of pleasure, sadness for the incapacity to give birth, guilt, sleeping disorders, excessive anxiety, difficulties in talking to many people.

DSM 5 Diagnosis

During the diagnostic phase, Beatrice was assessed as meeting DSM 5 diagnostic criteria of moderate Major Depressive Disorder, Anxious Distress, Dependent and Histrionic Personality Disorder. She experienced depressed mood most of the day, nearly every day, for more than two weeks (criterion A1), decreased interest and pleasure in sexual activities (A2), decrease in appetite (A3), insomnia (A4), and feelings of worthlessness (A7) and diminished ability to concentrate (A8). Beatrice also met DSM 5 diagnostic criteria of anxious disorder: she experienced excessive anxiety and worry occurring more days than not for at least 6 months (A), she finds it difficult to control the worry (B), her anxiety and worries are associated with feeling keyed up or on edge (1), irritability (4) and sleep disturbance (6). According to the alternative model for personality disorder in DSM 5 Section III, a personality diagnosis was also conducted. This diagnosis allows for assessment of: 1) the level of impairment in personality functioning, and 2) pathological personality traits. Beatrice showed moderate impairment in the level of organization in the areas of identity, self-direction, and intimacy. She showed also personality traits of: emotional lability, anxiousness, separation insecurity, submissiveness, depressivity, attention seeking and impulsivity.

The therapist also administered the Millon Clinical Multiaxial Inventory-III (MCMI-III) (Millon, Davis, & Millon, 1997), which highlighted high self-defeating and extremely high anxiety levels.

Case formulation

TA Diagnosis

Beatrice presented with Be Strong, Try Hard, Hurry Up and Please Others drivers (Kahler, 1975) and the injunctions (Goulding & Goulding, 1976) Don't think (when taking important decisions), Don't exist (without others), Don't be yourself (be the person others want), Don't be intimate (do not share feelings), Don't want (because you do not deserve), Don't make it (because you cannot), and Don't feel (be overwhelmed). Beatrice's Racket System (Erskine & Zalcman, 1979) showed beliefs such as "I am wrong", "Others are more important than me", "I cannot be angry with others". Her repressed authentic, primary feeling is anger toward herself and her mother, covered by substitute, secondary feeling of emptiness and disappointment (English, 1971). Interpersonally, Beatrice tends to alternate dramatic roles (Karpman, 1968) of Victim (she will always feel unhappy and there is nothing she can do to change this), and Rescuer (worrying and taking care of the problems of her partners). Her life position is generally I'm Not OK, You're OK (Ernst, 1971).

Treatment plan

The treatment plan primarily focused on creating a therapeutic alliance, providing permission (Crossman, 1966) congruent with the client's injunctions, namely: *think, exist, be yourself, be intimate, want, make it, and feel*. During pre-therapy sessions, the therapist focused on creating a solid therapeutic alliance and understanding that her problems generate from a hyper-adjustment and devaluation of her needs. Then, the therapist focused on decontamination and deconfusion. From session nine she instead focused more on reappraisal, and a partial loss elaboration for her impossibility to give birth. For the entire therapy, the therapy worked on supporting Beatrice's recognition of the importance of understanding her needs and emotions and feeling them, exploring her experiences and analysing her script events, such as the relationship she had with her mother when she was a little girl, and with her previous and current partners.

Contract

Beatrice asked to learn to weigh what she thinks and feels and act congruently according to these, to not devalue her thoughts and her emotions, and to do not let others decide these for her and tell her what to do. In session 12, Beatrice and the therapist agreed upon creating a new therapeutic contract "about the building of this story, to undertake a path towards being a parent... on the theme of adoption" (S12, Line 123-126).

Notes on the case

When Beatrice started therapy, she was living in a very complicated situation: her current partner was taking care of the sister of his dead ex-girlfriend and was very tied to her family, whereas Beatrice did not like this situation. The client wanted to have children with him and after many attempts, she asked for IVF. She had quite a few IVF, paying them on her own, because her partner believed it was her problem, her responsibility to try to get pregnant. He was not open minded about adoption, so having a biological child was the only solution Beatrice had with him. Furthermore, she was sent by the gynaecologist with a diagnosis of depression for her incapacity to have children, to work on her loss elaboration. However, the therapist believed the etiopathology of her depression consisted in her difficulty to express emotions and in her tendency to act impulsively, and therefore believed that her depression was not directly tied to her infertility, but that the infertility influenced her self-image crisis which worsened her symptoms. For this reason, the therapist worked mainly on her emotions, and only afterwards, from session 12, on her loss elaboration.

Hermeneutic Analysis Team

The HSCED main investigator and first author of this paper is a PTSTA-P with 15 years of clinical experience, with a strong allegiance for TA. Despite recent literature suggesting that hermeneutic analysis should be carried out by expert psychotherapists (Wall et al, 2016), we believe that such indication is suitable when the research is investigating a new population or a therapy that lacks a research base. In our case, we preferred to follow the indication of Bohart (2000), who proposed that analyses can be carried out by a team of 'reasonable persons', not yet overly committed to any theoretical approach or professional role. The team comprised of six postgraduate psychology students who were taught the principles of hermeneutic analysis in a course on case study research at the University of Padua, by Professor John McLeod. Following the indication of Elliott et al. (2009), the students preferred to assume both affirmative and sceptic positions, and independently prepared their affirmative and sceptic cases. Then they met and merged their own cases, supervised by the main investigator, creating consensual affirmative and sceptic briefs and rebuttals.

Judges

The judges were three researchers at the University of Padua and co-authors of this paper: Judge A, Vincenzo Calvo, clinical psychologist, psychotherapist trained in dynamic psychotherapy, PhD in development psychology, with expertise in attachment theory; Judge B, Stefania Mannarini, psychologist with experience in research methodology; and Judge C, Arianna Palmieri, neuropsychologist and psychotherapist with a training in dynamic psychotherapy. Judge A and C had some basic knowledge of TA but had never engaged in any official TA training, whereas Judge B has some clinical experience but no knowledge of TA.

Measures

Statistical Analysis

All quantitative outcome measures were evaluated according to Reliable and Clinically Significant Change (RCSC) (Jacobson & Truax, 1991), where 'change' stands for an improvement (RCSI) or for a deterioration (RCSD). Clinical significance (CS) is obtained when the observed score on an outcome measure drops below a cut-off score that discriminates clinical and non-clinical populations. The PHQ-9 considers a score of ≥ 10 as an indicator of current moderate major depression (Kroenke, Spitzer & Williams, 2001). It is important to consider that even below the cut-off score there may be a subclinical disorder. The PHQ-9 considers a score between 0 and 4 an indication of healthy condition, and a score between 5 and 9 as an indicator of mild (subclinical) depression. Reliable Change Index (RCI) is a statistic

that enables the determination of the magnitude of change score necessary to consider a statistically reliable change on an outcome measure (Jacobson and Truax, 1991). In particular, it is helpful in minimizing Type I errors which occur when cases with no meaningful symptom change are assumed to have improved. Richards and Borglin (2011) proposed that a reduction of at least 6 points in the PHQ-9 score would be indicative of a reliable improvement. Only when we observe the presence of both CS and RCI do we have RCSC, which is considered a robust method for assessing recovery in psychological interventions (Evans, Margison & Barkham, 1998; Delgado, McMillan, Leach, Lucock, Gilbody & Wood, 2014). To control experiment-wise error which occurs when multiple significance tests are conducted on change measures, we consider that a RCSC is required in at least two out of three outcome measures, thus demonstrating a Global Reliable Change (GRC) (Elliott, 2015).

Quantitative Measures

Four standardized self-report outcome measures were selected to measure primary (depression and anxiety) and secondary (global distress and personal problems) outcomes.

Patient Health Questionnaire 9-item for depression (PHQ-9) (Spitzer, Kroenke & Williams, 1999) scores each of the nine DSM 5 criteria from 0 (not at all) to 3 (nearly every day), providing a total score of depression. It has been validated for use in primary care (Cameron, Crawford, Lawton, et al, 2008). Scores up to 4 are considered healthy scores of 5, 10, 15 and 20 are taken as the cut-off point for mild, moderate, moderately severe and severe depression, respectively. PHQ-9 score ≥ 10 has a sensitivity of 88% and a specificity of 88% for major depression (Kroenke, Spitzer, & Williams, 2001) and scores of < 10 are considered subclinical. A change of at least 6 points on PHQ-9 score is considered to assess a reliable improvement or deterioration (RCI).

Generalized Anxiety Disorder 7-item for anxiety (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006) scores each of the seven DSM 5 criteria at 0 (not at all), 1 (several days), 2 (more than half the days), and 3 (nearly every day), respectively, providing a total score for anxiety. Scores of up to 4 are considered healthy, scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. Using the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for GAD and scores of < 10 are considered subclinical. GAD-7 is moderately good at screening three other common anxiety disorders - panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%) and post-traumatic stress disorder (sensitivity 66%, specificity 81%) (Kroenke,

Spitzer, Williams, et al, 2007). A change of at least 4 points on GAD-7 score is required in order to assess a reliable improvement or deterioration (RCI).

Clinical Outcome for Routine Evaluation - Outcome Measure for global distress (CORE-OM) (Evans, Connell, Barkham, Margison, Mellor-Clark, McGrath, & Audin, 2002) scores on a 5-point scale 34 items ranging from 0 to 4 (0 = not at all, 4 = most of the time). Scores up to 5 are considered healthy, up to 9 are considered low level (sub-clinical), and scores of 10, 15, 20 and 25 are taken as the cut-off point for mild, moderate, moderately severe and severe distress, respectively. The cut-off of 10 yields a sensitivity (true positive rate) of 87% and a specificity (true negative rate) of 88% for discriminating between members of the clinical and general populations. CORE OM was used in assessment sessions, in sessions 8, 16 and follow ups, whereas CORE short form A and B were used alternatively in the other sessions (Barkham, Margison, Leach, Lucock, Mellor-Clark, Evans, McGrath et al, 2001). A change of at least 5 points on CORE-OM score is required in order to assess a reliable improvement or deterioration (RCI).

The *Personal Questionnaire* (PQ) (Elliott, Shapiro, & Mack, 1999; Elliott, Wagner, Sales, Rodgers, Alves & Café, 2016) is a client-generated measure in which clients specify the problems they would like to address in their therapy and rate their problems according to how distressing they are finding each problem (1, not at all; 7, maximum possible). Scores up to 3.25 are considered subclinical. In this case series, missing the Italian normative score, for the PQ we adopted a more conservative RCI of two points, rather than the RCI of 1.67 recently proposed by Elliott et al. (2016). The PQ procedure suggests including problems from five areas: symptoms, mood/emotions, specific performance or activity (e.g., work), relationships and self-esteem/internal experience.

Qualitative Measure

The client was interviewed using the Change Interview protocol (CI) (Elliott, Slatick & Urman, 2001) one month after the conclusion of the therapy. The CI is a semi-structured qualitative change measure which asks clients how they feel they have changed during the therapy and how they think these changes came about, what they felt was helpful or hindering in the therapy, and what changes they feel they still need to make. Clients are asked to identify key changes they made and to indicate on a five-point scale: 1) if they expected to change (1=very much expected; 5=very much surprising); 2) how likely these changes would have been without therapy (1=very unlikely; 5=very likely), and 3) how important they feel these changes to be (1=not at all; 5=extremely).

The client also completed the Helpful Aspects of Therapy form (HAT) (Llewelyn, 1988) at the end of

each session. The HAT allows the client to describe hindering or useful aspects of the session and to rate them on a nine-point scale (1=extremely hindering, 9=extremely useful).

Therapist Notes

A structured session notes form (Widdowson, 2012a, Appendix 6, p. 50-52) was completed by the therapist at the end of each session. In this form, the therapist provides a brief description of the session in which they identify key aspects of the therapy process, the theories and interventions used, and an indication of how helpful the therapist felt the session was for the client.

Adherence

The therapist, the supervisor, and the main researcher were all transactional analysts and they each independently evaluated the therapist's adherence to TA treatment of depression using the Operationalized Adherence Checklist proposed by Widdowson (2012a, Appendix 7, p. 53-55) and agreeing on a final consensus rating.

HSCED Analysis Procedure

HSCED analysis was conducted according to Elliott (2002), and Elliott et al. (2009), as described in previous publications of this series (eg., Benelli, 2017c).

Adjudication Procedure

Each judge received the rich case record (Session transcriptions, therapist and supervisor adherence forms and session notes, data from quantitative and qualitative measures and a transcript of the CI) as well as the affirmative and sceptic cases and rebuttals by email, together with instructions. The judges were asked to examine the evidence and provide their verdict. They were required to establish via consensus:

- If the case were a clearly good outcome case, a mixed outcome case, or a poor outcome case;
- If the client had changed;
- To what extent these changes had been due to the therapy;
- Which aspects of the affirmative and sceptic arguments had informed their positions.

Furthermore, the judges had to observe which mediator factors in the therapy they considered to have been helpful and which characteristics about the client did they think had contributed to the changes as moderator factor.

Results

In earlier published HSCED's the rich case records, along with hermeneutic analysis and judges' opinions were often provided as online appendices (Benelli et al., 2015). Since all the material is in Italian language,

we adopted here the solution of providing a summary of the main points, as proposed in MacLeod, Elliott and Rodger (2012). The complete material (session transcriptions, CI, affirmative and sceptic briefs and rebuttal, judge opinions and comments) is available from the first author on request.

Adherence to the manualized treatment

The conclusion of the three evaluators was that the treatment had been conducted coherently according to TA theory at a good to excellent level of application.

Quantitative Data

PHQ-9, GAD-7 and CORE-OM were administered in the pre-treatment phase in order to obtain a three-point baseline, and during the three follow-ups, whereas PQ was first administered in session 0C.

Beatrice's quantitative outcome data are presented in Table 1. The initial depressive score (PHQ-9, 11) indicated a moderate level of depression. The initial anxiety score (GAD-7, 9.7) indicated a mild level of anxiety. The global distress score (CORE, 11.6) indicated a mild level of global distress and functional impairment. The severity score of personal problems (PQ, 5.3) indicated that the client perceived her problems as bothering her more than considerably.

At session 8, (mid-therapy), depression remained unaltered (11), anxiety increased to moderate level

(12), global distress increased to a moderate level (15.9), and personal problems decreased to little bothering (3.5).

By the end of the therapy, the depressive score passed to a mild range (7), anxiety obtained a clinically improvement passing to a mild level (7), global distress obtained a reliable and clinically significant improvement (RCSI) passing from a moderate to low level of distress (8.8), and the personal problems reached RCSI becoming very little bothering (2.7).

At the 1-month follow up: depressive scores remained in the mild range (7), anxiety score obtained a RCSI in the mild range (5), the global distress maintained its low level score (8.2), and personal problems remained as very little bothering (2.5).

At the 3-month follow up all scores improved obtaining RCSI: depression reached RCSI passing to a healthy range (0), anxiety passed to a healthy level (0), global distress entered healthy range (1.8), and personal problems became not bothering at all (1.1).

At the 6-month follow up depression, anxiety and global distress remained in the healthy range, maintaining clinically significant and reliable change, whereas personal problems became very little bothering (2), however still with RCSI. All measures maintained RCSI by the end of therapy.

	Pre-Therapy ^a	Session 8 Middle	Session 16 End	1 month FU	3 months FU	6 months FU
PHQ-9	11 Moderate	11 Moderate	7 (+) Mild	7 (+) Mild	0 (+)(*) Healthy	2 (+)(*) Healthy
GAD-7	9.7 Mild	12 Moderate	7 (+) Mild	5 (+)(*) Mild	0 (+)(*) Healthy	0 (+)(*) Healthy
CORE-OM	11.6 Mild	15.9 Moderate	8.8 (+)(*) Low level	8.2 (+)(*) Low level	1.8 (+)(*) Healthy	4.1 (+)(*) Healthy
PQ	5.3^b Considerably	3.5 Little	2.7 (+)(*) Very little	2.5 (+)(*) Very little	1.1 (+)(*) Not at all	2 (+)(*) Very little

Note. Values in **bold** are within the clinical range; + indicates clinically significant change (CS). * indicates reliable change (RC). FU = follow-up. PHQ-9 = Patient Health Questionnaire 9-item for depression (Spitzer, Kroenke & Williams, 1999). GAD-7 = Generalized Anxiety Disorder 7-item (Spitzer, Kroenke, Williams, & Löwe, 2006). CORE = Clinical Outcomes in Routine Evaluation-Outcome Measure (Evans et al., 2002). PQ = Personal Questionnaire (Elliott, Shapiro, & Mack, 1999). Clinical cut-off points: PHQ-9 ≥10; GAD-7 ≥10; CORE-OM ≥10; PQ ≥3.25. Reliable Change Index values: PHQ-9 variations of six points, GAD-7 variation of four points, CORE-OM variation of five points, PQ variation of two points.

^aMean score of pre-treatment measurements.

^bFirst available score in session 0C.

Table 1: Beatrice's Quantitative Outcome Measure

	PQ items	Duration	Pre-Therapy ^a	Session 8 (middle)	Session 16 (end)	1 month FU	3 months FU	6 months FU
1	I've many feelings of guilt that I'm not able to deal with	6-10y	5 Considerably	5 Considerably	2 (+)(*) Very little	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all
2	I've the feeling that I'll always be sad and that there is no way to solve this situation	6-10y	6 Very considerably	4 (*) Moderately	4 (*) Moderately	3 (+)(*) Little	1 (+)(*) Not at all	2 (+)(*) Very little
3	I've difficulties in planning my future	>10y	7 Maximum possible	4 (*) Moderately	4 (*) Moderately	4 (*) Moderately	1 (+)(*) Not at all	3 (+)(*) Little
4	I'm angry because life deprived me of the joy of being a mother	>10y	7 Maximum possible	4 (*) Moderately	4 (*) Moderately	5 (*) Considerably	2 (+)(*) Very little	5 (*) Considerably
5	I'm not able to adapt myself to some daily social circumstances (i.e. spend time with people I don't like)	6-10y	5 Considerably	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all
6	In the current time my sexual desire is lacking ("I've difficulties to make love for myself")	1-2y	7 Maximum possible	2 (+)(*) Very little	2 (+)(*) Very little	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all
7	I'm worried for the future of my relationship ("I'm not able to see myself in a couple without kids, maybe I should stay single?")	1-2y	7 Maximum possible	4 (*) Moderately	5 (*) Considerably	2 (+)(*) Very little	1 (+)(*) Not at all	1 (+)(*) Not at all
8	I'm not able to believe in my work abilities	>10y	5 Considerably	2 (+)(*) Very little	1 (+)(*) Not at all	3 (+)(*) Little	1 (+)(*) Not at all	2 (+)(*) Very little
9	I struggle to assume my responsibilities	>10y	4 Moderately	5 Considerably	4 Moderately	3 (+) Little	1 (+)(*) Not at all	2 (+)(*) Very little
10	I've sudden states of anxiety, especially during the night	1-2y	4 Moderately	2 (+)(*) Very little	2 (+)(*) Very little	2 (+)(*) Very little	1 (+)(*) Not at all	1 (+)(*) Not at all
Cont/								

	PQ items	Duration	Pre-Therapy ^a	Session 8 (middle)	Session 16 (end)	1 month FU	3 months FU	6 months FU
11	I feel awkward talking in front of an audience	>10y	4 Moderately	5 Considerably	2 (+)(*) Very little	4 Moderately	1 (+)(*) Not at all	4 Moderately
12	I suffer because mom disappointed me	>10y	3 Little	4 Moderately	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all	1 (+)(*) Not at all
	Total		64	42	32	30	13	24
	Mean		5.3 Considerably	3.5 Little	2.7 (+)(*) Very little	2.5 (+)(*) Very little	1.1 (+)(*) Not at all	2 (+)(*) Very little

Note. Values in **bold** are within clinical range. +=indicates clinically significant change (CS). *=indicates reliable change (RCI). m = months. y = year. FU= follow-up. PQ = Personal Questionnaire (Elliott, Shapiro, & Mack, 1999). Clinical cut-off point: PQ ≥3.25. Reliable Change: PQ variation of two points. The rating is on a scale from 1 to 7 and indicate how much each problem has bothered the client: 1 = not at all; 7 = maximum.

^aThe first available score was in session 0C.

Table 2: Beatrice's personal problems (PQ), duration and scores

Session	Rating	Events	What made this event helpful/important
1	9 (extremely)	The therapist asked me to explain and understand how I feel.	I feel, now, <u>aware</u> about what I feel which must be understood for what it is, namely myself.
2	8 (greatly)	The event is tied to a request of the therapist about my lack of trust in myself in important situations. I don't act according to what I know I want.	It has been possible to reinterpret some events/behaviours from another perspective. It's not easy to mirror and immediately see yourself for what you are. It's something which I have many difficulties in doing, but that I feel useful for me.
3	8 (greatly)	The session has been very intense. Repeatedly I had the sensation of falling through space and losing myself in the incapacity of coming to decisions and the opposite sensation to be able to do and decide what I want in my life	The therapist felt my insecurity and helped me to look inside me from different sides. The important event and what made it so important has been when I asked the therapist to help me to come to decisions and instead I understood that everything depends on me.
4	8 (greatly)	The last session has been narrative (coming back from the summer break). I found myself giving explanations and telling important events that changed my life in the last month. I came to some important decisions that make me feel good.	It's nice to stay with yourself.
			Cont/

Session	Rating	Events	What made this event helpful/important
5	9 (extremely)	During the session we talked about the management of the end of my relationship and, even though until last week I was feeling that I was satisfying myself by that decision and facing it, I understood that I'm repeating some behaviours and ways of agreement with my ex-partner, which give me anger, a feeling of suffocation and the feeling that I'm being managed by others, which should be appropriate to deal with.	First of all, I immediately reacted and came to some decisions I felt right until the session. I don't like not being able to control myself any more and subordinating my desires to others' expectations.
6	9 (extremely)	During the current session I spoke about an emotion which made me call into question important decisions. Solicited by the psychologist I recalled similar situations where the emotions (positive and negative) led me to not thoughtful decisions.	I understood that I need to learn to deal with/accept/live with/understand the emotions of this type without feeling at the mercy of them.
7	7 (moderately)	The therapist prompted me to reflect about my perception of having always made people who loved me suffer, especially my men.	I recalled the events tied to different moments of my life. Especially, my relationship with my mother. I feel extreme difficulty to talk about my mother like the responsible or the cause of some problematics tied to the growth of my personality. It's something that doesn't put me at ease and gives me feelings of guilt.
8	-	It's been a very complicated session. It's difficult to describe an event, maybe the entire session was an event. I felt emotionally fragile especially when the therapist asked me to give voice to the mom inside me.	I'm not sure what I got out of this. I felt in a liquidiser of different emotions. Sadness for being a missed mother. Anger because I'd want to be a less severe mother with myself. I've also felt an inadequate mother because I'm unable to give myself the self-confidence I need.
9	8 (greatly)	During the session I talked about an episode of my childhood after which I started to use some strategies that the therapist defined as "adaptive solutions", explaining to me what it meant.	I realized that until today I apply "adaptive solutions" in order to try to face difficulties and emotionally complicated situations that I'm not able to resolve and deal with in other ways. I understood that I don't like these situations and adaptive behaviours anymore. I understood that I don't want to adapt but face situations and people engaged in a more mature way.
10	8 (greatly)	During the session we discussed about my difficulty to face the situations when I imagine all possible scenarios. The tendency is to imagine only the extremity (white or black). The therapist made me notice that it's possible to think for intermediate steps and then face complex situations with different methods from the ones I currently use.	It has been useful especially because it gave me the possibility to behave in different ways, which considerably decreased my anxious states, whereas my solutions made them increase.
			Cont/

Session	Rating	Events	What made this event helpful/important
11	8 (greatly)	We faced the theme of maternity and of my suffering for the possibility to become a mother, naturally or biologically, and of the fear to imagine a different solution for me, like adoption.	The important event consists in understanding that imagining this different possibility for me is the beginning of a probable path. Nevertheless, it's a thought that tastes like planning the future. A constructive attitude that, beyond its realization, makes me feel good.
12	9 (extremely)	The most important event has been gaining the awareness of my capacity of calling myself into question and of being ready to change my life (house, job, city) in order to follow a goal, a project. Maybe it's the awareness of the fact that I can have a project to be the <u>event</u> for me.	The event is extraordinarily useful because I had a strong feeling that I'm still able to breath with my lungs. To take deep breaths and look at my future life with curiosity and joy. I don't have that feeling of being condemned to unhappiness and loneliness anymore.
13	8 (greatly)	During the session we discussed about the relationship between me, my partner and his son. In particular, I focused that I have to protect myself not only from the daydream, but also to build a family unit. The event consists in identifying brightly that mom, dad, and son are a family.	I understood that lately I have to work on that aspect of my relationship. I feel that I need to protect myself from false illusions, that give me great suffering.
14	8 (greatly)	During the session we mainly discussed about the relationship between me, my partner and his son and to the right attention I have to give to the emotional part to deal with this relationship. I wouldn't say that an event occurred, even though I clarified further the critical aspects that need to be clarified and faced to maintain my relationship and myself from unsolved business and never fully examined.	The discussion certainly helped me to consider with more attention the important elements to build a relationship.
15	8 (greatly)	In particular, a question struck me, also frequent even in other sessions, which is to try to understand how I feel about events that concern me personally.	What strikes me every time but this time with more evidence, is the difficulty that I have when they ask me this question. It's difficult for me to read inside myself, because sometimes what I feel, how I feel, do not correspond with what I'd want or I should feel and I feel inconclusive and immature.
16	8 (greatly)	It struck me about the question of the therapist about my method of coming to the decision of breaking up a relationship and to my decisions at the bottom of these breaking ups.	I understood that I come to decisions according to strong emotions that determine them and that change reality or the perception that I have in a very short time. I have to give myself the possibility to understand the weight and the importance of the emotions I feel in order to come to a decision in a more tranquil way.

Note. The rating is on a scale from 1 to 9: 1 = extremely hindering, 5 = neutral, 9 = extremely helpful. HAT = Helpful Aspect of Therapy (Llewelyn, 1988).

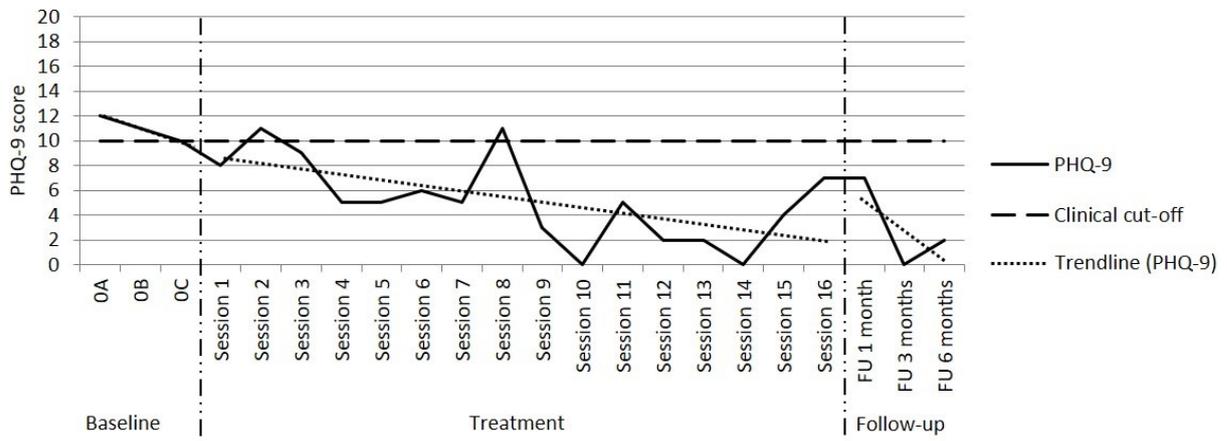
Table 3: Beatrice's helpful aspect of therapy (HAT forms)

	Change	How much expected change was ^(a)	How likely change would have been without therapy ^(b)	Importance of change ^(c)
1	I'm able to have no feelings of guilt	1 (very much expected)	1 (very unlikely)	5 (extremely)
2	Plan the future	5 (very much surprised)	3 (neither likely nor unlikely)	5 (extremely)
3	I'm able to deal with strong emotions	1 (very much expected)	1 (very unlikely)	5 (extremely)
4	I have no more anxious states (panic)	1 (very much expected)	1 (very unlikely)	4 (very)
5	I've been able to assume the responsibility for my decisions	1 (very much expected)	1 (very unlikely)	5 (extremely)

Note. CI = Change Interview (Elliott et al., 2001).

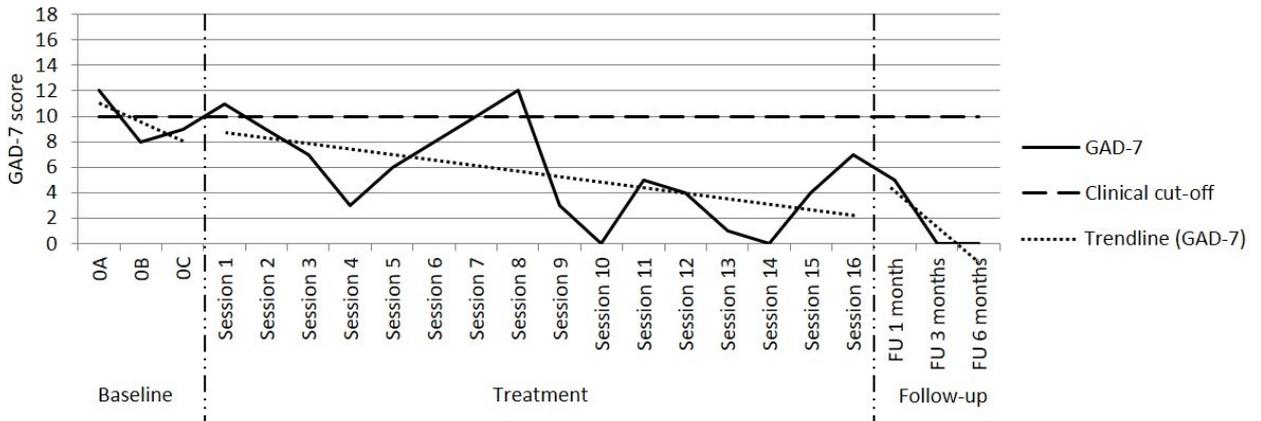
^aThe rating is on a scale from 1 to 5; 1 = very much expected, 3 = neither, 5 = very much surprising. ^bThe rating is on a scale from 1 to 5; 1 = very unlikely, 3 = neither, 5 = very likely. ^cThe rating is on a scale from 1 to 5; 1 = not at all, 3 = moderately, 5 = extremely.

Table 4: Beatrice's Changes identified in the Change Interview



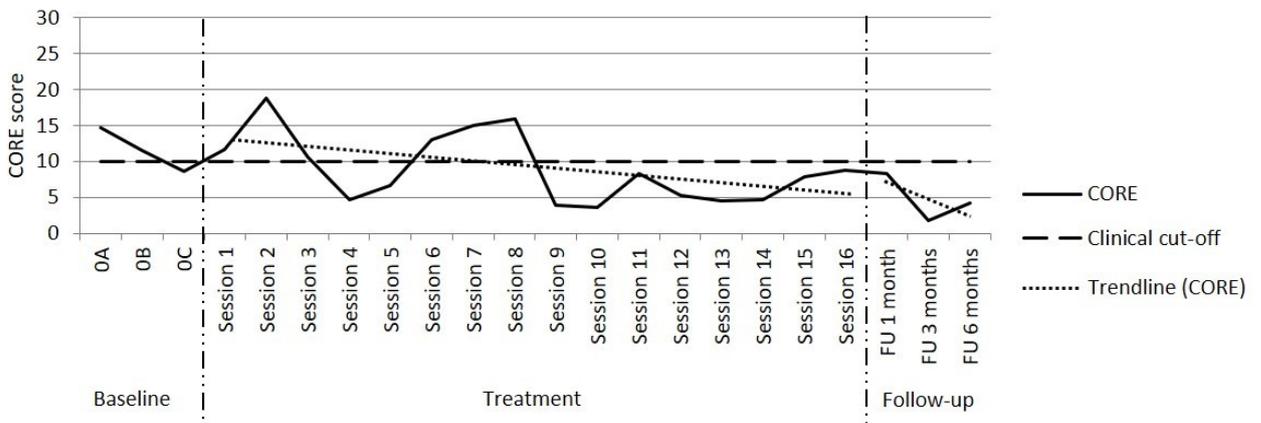
Note. 0A, 0B and 0C = assessment sessions. FU = follow-up. PHQ-9 = Patient Health Questionnaire 9-item for depression (Spitzer, Kroenke & Williams, 1999).

Figure 1: Beatrice's weekly depressive (PHQ-9) score



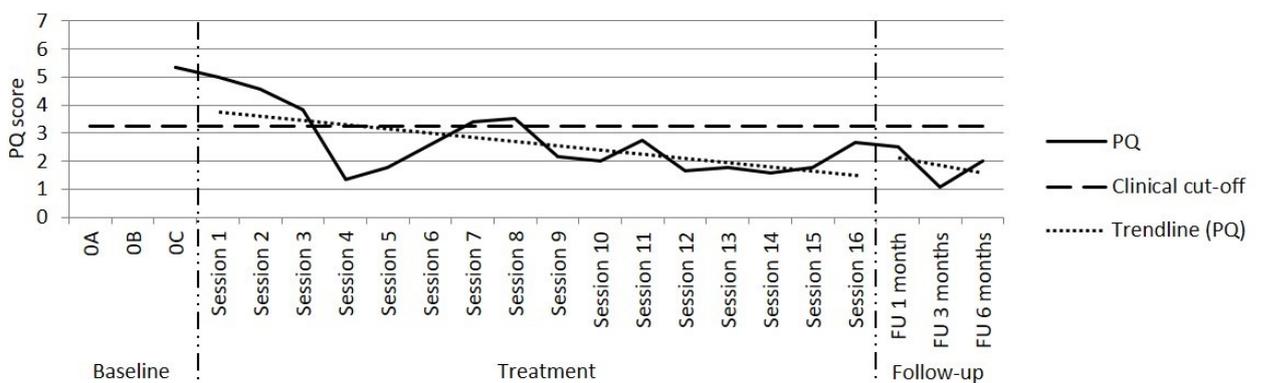
Note. 0A, 0B and 0C = assessment sessions. FU = follow-up. GAD-7 = Generalized Anxiety Disorder 7-item (Spitzer, Kroenke, Williams, & Löwe, 2006).

Figure 2: Beatrice's weekly anxiety (GAD-7) score



Note. 0A, 0B and 0C = assessment sessions. FU = follow-up. CORE = Clinical Outcomes in Routine Evaluation-Outcome Measure (Evans et al., 2002).

Figure 3: Beatrice's weekly global distress (CORE) score



Note. The first available score was in assessment session 0C. 0A, 0B and 0C = assessment sessions. FU = follow-up. PQ = Personal Questionnaire (Elliott, Shapiro, & Mack, 1999).

Figure 4: Beatrice's weekly personal problems (PQ) score

Table 2 shows the 12 problems that the client identified in her PQ at the beginning of the therapy and their duration. Four problems were rated as maximum possible bothering, one was rated very considerably, three considerably bothering, three were rated moderately bothering, and one little bothering. Six problems lasted from more than 10 years, three as lasting from 6 to 10 years, and three as lasting from 1 to 2 years. Seven out of twelve problems showed a clinically significant and reliable change by the end of the therapy and four obtained reliable change. In the 1-month follow up nine problems reached RCSI and two obtained reliable change whereas all problems reached a clinically significant and reliable change in the 3-month follow up. In the 6-month follow-up, ten problems maintained clinically significant and reliable change.

Problems are related to: symptoms (1 guilt, 10 anxiety); mood/emotions (2 sad, 4 angry, 6 sexual desire lacks, 12 suffer); specific performance/activity (8 work abilities, 11 talking to an audience); relationships (5 adapt to social circumstances, 7 worried for relationship); self-esteem and inner experience (3 planning future, 9 responsibilities).

Figures 1 to 4 allow visual inspection of the time series of the weekly scores of primary (PHQ9, GAD-7) and secondary (CORE and PQ) outcome measures, with linear trendline.

Qualitative Data

Beatrice compiled the HAT form at the end of every session (Table 3), reporting only positive/helpful events. All positive events were rated from 7 (moderately helpful) to 9 (extremely helpful) as reported in Table 3. Beatrice also reported other helpful events in session 5 ("The therapist asked me why I thought about the IVF like a path/problem that was only about me and not the couple. The question was asked because I thought I had to deal with the costs on my own"), 7 ("Always about my relationship with my mother, I had the opportunity to reflect on my thoughts of use I made with truth/lies in my interpersonal relationships"), and 12 ("The event consists in creating a new therapy contract with the therapist. The contract is about my path towards the possibility to face with my partner the creation of our family through adoption"). She reported aspects on:

- symptoms (HAT 10, "decreased my anxious states");
- mood/emotions (HAT 1, "understand how I feel"; HAT 3, "sensation of falling through space"; HAT 6, "deal with emotions"; HAT 8, "liquidiser of emotions"; HAT 12, "no more condemned to unhappiness"; HAT 15, "what I feel, how I feel"; HAT 16, "come to decisions according to strong emotions");

- relationships (HAT 9, "I don't want to adapt"; HAT 14, "critical aspects that need to be clarified and faced");
- self-esteem and inner experience (HAT 2, "lack of trust in myself"; HAT 4, "decisions that made me feel good"; HAT 5, "don't like subordinating what I want"; HAT 7, "difficulty to talk about my mother like the responsible"; HAT 11, "planning future makes me feel good"; HAT 13, "protect myself from day dreams/illusions").

Beatrice participated in a Change Interview 1 month after the conclusion of the therapy. In this interview, she identified five main changes (Table 4). She was very much surprised (5) by one but was not sure whether this was due to therapy (3). Beatrice very much expected (1) four changes, that would have unlikely occurred without therapy (1), and rated one change as very important (4) and four changes as extremely important (5).

HSCED Analysis

Affirmative Case

The affirmative team identified four lines of evidence supporting the claim that Beatrice 1) changed and that 2) therapy had a causal role in this change.

1. Change in stable problems

Quantitative data (Table 1) shows that there is an improvement in primary outcome measures: depression (PHQ9) with RCSI from session 9 until session 15, regained in the 3-month follow up; anxiety (GAD-7) reached RCSI in session 9 until session 15, re-obtained in the 1-month follow up. There is also RCSI in personal problems (PQ, Table 2) from session 9, maintained until the end of therapy and in the follow-up period. In her PQ, Beatrice identified 12 main problems at the beginning of the therapy that she was trying to solve, four rated as bothering her maximum possible (7), one very considerably (6), three considerably (5), three moderately (4) and one little. All the problems referred to issues with symptoms, mood/emotions, specific performance/activity, relationships, and self-esteem and inner experience. At the end of the therapy seven problems out of twelve dropped under the clinical cut off reaching RCSI, and four other problems gained reliable improvement. At the 1-month follow up, ten problems reached reliable change and nine gained also clinical improvement. At the 6-month follow up all problems gained RCSI. Overall, there is support for a claim of global reliable change (reliable change in four out of four measures) for long standing problems. Qualitative data supports this conclusion: in the Change Interview, Beatrice reports that "there have been many changes" (Line 417). Regarding her depressive symptoms, she stated: "before I thought that anything was my fault, now I understood that this is not true" (L187-192), and that she has no more feelings of guilt, an aspect that

gained a stable RCSI in her PQ in session 12, maintained throughout the follow-ups. About anxiety symptoms, she explained: "I'm not suffering with anxiety attacks" (L364), "when I started therapy my anxiety was the highest possible... there has been an improvement" (L417-421). Beatrice also reported changes in her emotions: about her anger for the inability to become a biological mother, she said "I'm not angry anymore, I'm trying to live with this" (CI, L412-415). She added that making love (item 6 of the PQ) "is not a problem anymore" (L405). Moreover, during therapy, Beatrice realized that she has always acted following strong emotions she currently felt, whereas now she gives herself the permission to think, to be aware and to be able to deal with these emotions (L444-447): "I listened [to the therapist] and followed your advice, giving me the time to think without coming to any quick decision based on emotions" (FU1, L3-5), "with hindsight I could have taken this time even in the past" (L22-23). Regarding Beatrice's difficulties in relationships (item 5 of the PQ), she stated: "I thought I was antisocial, now I don't have these problems anymore... the meaning of this item changed" (L355-357). Finally, according to Beatrice's self-esteem problematics, she reported different changes. First of all, she said "I make more thoughtful decisions, before therapy everything seemed a tragedy... I had the incapacity to deal with confrontations... terror... now it's a lot less" (L67-72). Second, that she learnt "a different capacity to understand myself, I'm more tranquil when facing problems that first I believed to be insurmountable (CI, L455-458). At last, in her CI she rated being able to plan the future (item 2 of the CI, also present as item 3 in the PQ) as an extremely important (5) change she was trying to solve for more than 10 years. Thus, we claim that Beatrice obtained a stable RCSI in Major Depressive Disorder, in anxiety, in global distress and in personal problems, claiming a Global Reliable Change.

2. Retrospective attribution

In her Change Interview, Beatrice looked back at her PQ, and reported that four out of five main changes would have very unlikely occurred without therapy. (Table 4). Beatrice was very much surprised by only one change ("plan future"), which she is not sure whether this is due to therapy or not, however rating it as extremely important. In her HAT forms (Table 3, i.e. S5, "the therapist asked me why I thought about IVF like a path/problem that was only about me"; S9, "I started to use some strategies that the therapist defined as 'adaptive solutions'"; S10, "the therapist made me notice that it's possible to think for intermediate steps"; and S15, "a question... which is to try to understand how I feel") Beatrice reported some interventions of the therapist that reflect changes in her way of behaving and coping with herself. Regarding her symptoms, in her CI she attributed to

therapy having no feelings of guilt, and no more anxious states (very unlikely without therapy). About her mood/emotion problematics, she reported that "with the therapist I've been able to know myself... that I act following strong and impulsive emotions without reflecting... whereas now I reflect" (L54-61). The questions of the therapist forced me to reflect, to understand and adapt (L279-281), "she told me 'it seems like you are giving up living in the present'... it's like if she opened a gash... when you hear it, you realize that it's exactly true" (L296-300). Furthermore, "the therapist told me things that made me feel and understand what I felt and how I should have felt... I obtained self-awareness" (L305-308). In session 12, Beatrice stated that therapy also helped her in her relationship: "the work we are doing here on me, is useful for the couple, this is the difference from previous relationships" (S12, L275-279). Finally, according to her CI, Beatrice attributed to therapy also changes in self-esteem: "therapy has been useful for me in order to exchange views, understand things about me (CI, L35), "exchanging views with someone makes you realize that your perception of some problematic aspects is different" (L41-42), "feeling that there was someone that listened to me and took care of me by asking me 'how do you think to take care of this?'... she threw me into crisis because I've never thought about taking care of myself" (L312-316).

3. Association between outcome and process (outcome to process mapping)

A change in Beatrice's problematic area of mood/emotions, which was her therapeutic contract, has been observed. She learnt to give herself time to think before acting according to strong emotions, which is mirrored to specific interventions of decontamination and reappraisal in seven HAT forms (Table 3), specifically in HAT 1, ("understand how I feel"), HAT 3 ("sensation of falling through space"), HAT 6 ("deal with emotions"), HAT 8 ("liquidiser of emotions"), HAT 12 ("no more condemned to unhappiness"), HAT 15 ("what I feel, how I feel"), HAT 16 ("come to decisions according to strong emotions"). Furthermore, Beatrice reported changes in self-esteem which allowed her to increase her self-esteem and be able to cope more with her dependency traits, reflected in insights during session reported in six HAT forms: HAT 2 ("lack of trust in myself"), HAT 4 ("decisions that made me feel good"), HAT 5 ("don't like subordinating what I want"), HAT 7 ("difficulty to talk about my mother like the responsible"), HAT 11 ("planning future makes me feel good"), HAT 13 ("protect myself from day dreams/illusions").

4. Event-shift sequences (process to outcome mapping)

The PQ mean score shows a progressive decrease in severity of her problems from the initial score (5.3,

more than considerably) to the final score (1.1, not at all bothering). In session 1, they worked on Beatrice's difficulty in spending time with people she does not like (PQ, item 5) connecting with an episode that had occurred in the previous week. From this event until session 8, the therapist connected to Beatrice's low self-esteem and her dependency traits focusing on helping Beatrice becoming more aware of how she decides to give no importance to her needs (model of Schiff, from therapist's notes, S1). Especially in session 8 the therapist asked Beatrice how she felt (L509): "scared" (L513), and the therapist continued "what do you do with a frightened child?" (L514), she answers "you reassure him" (L515), "how can you do that without denying your own thoughts and needs?... if you had been in his [her partner] situation, what would you have done?" (L516-524). In fact, in the 1-month follow up, Beatrice reports having understood that what she wanted was not finding a place where she could live on her own, but finding a way to recover things she feels she needs (FU1, L52-56). In the second part of the therapy, the therapist focused more on Beatrice's emotions and on reappraisal techniques, giving Beatrice the awareness that her partner's child is not their son, and on giving Beatrice the permission to imagine other possible scenarios in which she could be the mother of someone, through adoption. In fact, when her partner's child called her "mom" and her partner was happy for it, she realised that that was inappropriate and protected herself from further contamination and tangling with others' emotions and wishes (FU1, L256-257). Furthermore, Beatrice arrived in session 16 very discouraged, with the intention to break up with her partner on that same night. During the session they worked on her tendency to follow the current strong emotion without reflecting on her needs and wishes. This led Beatrice to the thoughtful decision of not following those strong emotions on the spot, and at the 3-month follow up she confirmed to have "maintained her commitment with herself" (FU2, therapist notes). Moreover, for the entire therapy the therapist focused on decontaminating her belief that she makes everybody suffer who loves her, especially men. The affirmative team believes that empathic listening has been fundamental for Beatrice to improve in problematic areas of emotions and self-esteem: "feeling that there was someone that listened to me and took care of me" (CI, L312-314). Beatrice also reported that therapeutic interventions made her "feel and understand what I felt and how I should have felt" (CI, L305-307). Furthermore, the therapist nourished Beatrice's independent traits, giving her the permission to believe in herself and in her emotions, allowing her to feel her own emotions, and not others'. This is reflected in HAT 2 ("request of the therapist about my lack of trust in myself"), and 3 ("the therapist felt my insecurity and helped me to look inside me... when I asked the therapist to help me to come to

decisions and instead I understood that everything depends on me").

Sceptic Case

1. The apparent changes are negative (i.e., involved deterioration) or irrelevant (i.e., involve unimportant or trivial variables).

The client entered the trial with moderate depression (PHQ-9, score 11), barely over the threshold for major depressive disorder and mild level of anxiety (GAD-7, score 9.7). Besides, all measures have a sawtooth wave trend, which might reflect Beatrice's affective lability, therefore quantitative data might be unreliable. Furthermore, all measures RCSI in session 4, after having broken up with her current partner, turned to pre-therapy or higher in session 8, when her ex-partner was leaving the State and she thought that her current partner would not have allowed her to go to a goodbye dinner with his friends, and then dropped back to RCSI in the following session. Moreover, the sceptic team found different contradictions in the client's data. In the CI protocol, she wrote "plan future" as one of the main changes, whereas during the interview she reported "I have many difficulties in thinking... planning the future" (CI, L102), and in her PQ the score to item 3 ("I've difficulties in planning my future") was rated as moderately bothering (4). Furthermore, Beatrice reported to have started to try to have kids from two years ago, and that when she got pregnant ten years before she did not want to have children. For this reason, the sceptic team believes that the duration of the fourth item of the PQ is not 'from more than 10 years' but more probably 'from 1 to 2 years', supporting the hypothesis that quantitative measures might be unreliable. Qualitative data reflects absence of change and no attribution to therapy for Beatrice's problematic areas. She reported that she found useful having someone that listened to her (CI, L312-314), therefore it is possible that therapeutic techniques might not have been the cause of any improvement in Beatrice. She also stated that she was not feeling at ease when talking in a negative way about her mother (CI, L325-330), an aspect that led to a break up in the therapeutic alliance in session 7. Regarding Beatrice's mood/emotion problems, during therapy she did not face her difficulty noted on item 6 ("In the current time my sexual desire is lacking"), which vanished since she met the man for which she left her partner between sessions 3 and 4. Moreover, she reported having sought therapy to alleviate the suffering of not being able to have any biological child (CI, L202-204), which has been faced in the specific only from session 12, leading to no reliable improvement since the new therapy contract, and still being "a little bit emphasized" (L227) in the 1-month follow up. About her problems in specific performance/activity, Beatrice and the therapist did not work on both of those items of the PQ, respectively

item 8 (“I’m not able to believe in my work abilities”) and 11 (“I feel awkward talking in front of an audience”), and in the CI she stated “I’m considered quite good in my job but I don’t have this feeling of myself, I don’t like talking to an audience... it puts me in extreme difficulty and embarrassment” (CI, L141-143), therefore any improvement in these items cannot be due to therapy. Finally, Beatrice’s dependence traits of personality did not change, which is mirrored in her still present tendency and script behaviour to break up every unhappy relationship only after having met another man, just like she left every previous partner.

2. The apparent changes are due to statistical artefacts or random errors, including measurement error, experiment-wise error from using multiple change measures, or regression to the mean.

All quantitative data baseline showed a decrease already in the assessment phase, which could lead to the conclusion that change would have happened anyway, even without therapy.

3. The apparent changes reflect relational artefacts such as global ‘hello-goodbye’ effects on the part of a client expressing his or her liking for the therapist, wanting to make the therapist feel good, or trying to justify his or her ending therapy.

In her CI, the client reported no hindering aspects of therapy (CI, L322-323), and in the HATs she never pointed out any hindering aspect, not even when the therapist tried to work on her early age problematics with her mother in session 7, leading to a break-up in the therapeutic alliance. In fact, the sceptic team believes that quantitative data is unreliable not only for Beatrice’s dependency traits, but also for her tendency to be compliant with others because of her fear of losing the relationship whenever she expressed different emotions and behaved differently from what she believed others expected. Her tendency to ‘Please Others’ might be at the base of her scores’ decrease in all quantitative measurements in the follow ups. In fact, in the CI she said that she had no suggestions for the therapy because “the therapist has been very good, so there is no need” (CI, L340-341). Furthermore, this ‘compliance effect’ is mirrored in all Beatrice’s HATs, where she rated fourteen sessions from ‘greatly’ to ‘extremely’ helpful, whereas in the therapist’s notes all sessions are rated ‘slightly’ or ‘moderately’ helpful.

4. The apparent changes are due to cultural or personal expectancy artefacts; that is, expectations or scripts for change in therapy.

In her CI, the client reported four problems out of five as ‘very much expected’, therefore it is probable that expectancy artefacts are at the base of Beatrice’s apparent changes. Furthermore, an immediate decrease in quantitative data from the assessment

phase might also be explained with her extreme faith in therapy. Moreover, the client has been sent to the therapist from her gynaecologist as a support for her incapacity to have biological children, so for this reason she could have had expectations thanks to the medical advice.

5. There is credible improvement, but this involves a temporary initial state of distress or dysfunction reverting to normal baseline via corrective or self-limiting processes unrelated to therapy.

According to the considerations made in the first sceptic point, Beatrice sought therapy to solve her impossibility to be a biological mother, which was lasting from no more than one month before the beginning of therapy. Her depressive and anxious state seems tied to this biological incapacity, therefore Beatrice’s diagnosis could be incorrect. The sceptic team suggests an adjustment disorder diagnosis: the client discovered her impossibility to give birth straight before beginning therapy, which might have led to a self-image crisis and consequentially to depressive and anxious symptoms. However, during therapy, Beatrice and the therapist did not work on this problem until session 12, and the PQ item (4) tied to this problematic remained mainly over the clinical cut off for thirteen sessions, and also in the 1-month follow up, whereas her depressive and anxious state decreased. Any loss elaboration for the impossibility to be a biological mother is not due to therapeutic interventions, but to the reverting to a normal baseline thanks to the flow of time. Therefore, Beatrice might have improved without therapy.

6. There is credible improvement, but it is due to extra-therapy life events, such as changes in relationships or work.

In the CI she stated that “my life has changed generally... I’m not sure how much is due to therapy, I haven’t understood this” (CI, L49-51). In particular, as already explained in the first point of this case, it seems that Beatrice is at the mercy of the many extra-therapeutic events that happen and involve her personally. Beatrice left her partner with whom she was having many different problems (planning future with him, living with him, his consideration that infertility was only her problem, his strong attachment to his dead ex’s sister and family, her anxieties at night correlated to her lack of desire to have sex with him, their difficulty in communicating and listening to each other’s need and wishes) and started a relationship with a man that she felt to be very close to her needs, who gave her the attention she needed, and who understood straight away her emotions. In fact, there is RCSI from session 4 (when she left her previous partner). Furthermore, when Beatrice moved to a new house to live on her own for the first time in her life, she reported feeling independent and happy (S10, L43). Moreover, in session 12 she received a marriage

proposal in order to have the possibility to ask for adoption, which might have led to a reversal of the crisis of Beatrice's self-image, and an improvement in quantitative measurements might be due to extra-therapeutic events.

7. There is credible improvement, but it is due to psychobiological processes, such as psychopharmacological mediations, herbal remedies, or recovery of hormonal balance following biological insult.

At the beginning of the treatment, Beatrice used to take alprazolam for her anxiety and difficulties in sleeping at night (CI, L31). Therefore there is no evidence that improvements in the client are tied to therapeutic interventions and not to psychopharmacological effects.

8. There is credible improvement, but it is due to the reactive effects of being in research.

The histrionic and dependent traits of the client could have had a role in Beatrice's CI due to the presence of a different person. Furthermore, Beatrice reported to have started working as a researcher for a short period of her life, and this might have led her to be compliant to research itself.

Affirmative Rebuttal

1. We claim that four out of four measures support a claim in favour of Global Reliable Change. Even if the sceptic team believes that Beatrice was at the mercy of extra-therapeutic events, and, therefore, that quantitative measurements are unreliable, according to the therapist's clinical experience the client satisfied DDM and anxiety disorder criteria. The therapist also administered Beatrice the MCMI-III, which highlighted high self-defeating and extremely high anxiety levels. Furthermore, Beatrice was prescribed alprazolam for her anxious states, her PQ item regarding anxiety was high, so anxiety is differently measured with different instruments. Moreover, not only are Beatrice's problems structural, but she has high level borderline functioning (Kernberg), and 16 sessions therapy are not sufficient for these kind of problematics. Regarding her difficulties in planning the future that she cited during the CI, she was referring to her own description: "for all my life I had this image of me, with kids... to do things with a family... well I can still have a family, but with adoption, and this leads to difficulties in planning the future... I changed the image I had of me... I feel different" (CI, L99-104). In fact, adoption is a long and complicated journey and Beatrice knows that: "it's possible, but it's not easy... it's a journey you have to do with serenity, we need to settle a little bit more first" (S11, L122-123), "there are many things that have to be done first... marriage... there is time... talking about adoption with someone you met three months ago it's a little bit premature" (L144-146). About the sceptic challenge on the duration of the fourth item, the affirmative team rebuttal is based on Beatrice narration

in session 0B: "I felt nothing until I woke up after the abortion... I remember it like it was yesterday... I focused on that and I felt completely empty, all my body, from my head to my feet, and then I understood... that I did a very serious thing, I was only thinking that I didn't want a child from a man I didn't love... I was not ready to be a mother, but I didn't think about it the way I should have" (S0B, L258-275). Moreover, there is no evidence that Beatrice never wanted to have kids after the abortion, so her frustration could have been present from more than ten years, like she scored in the PQ Duration Form. The sceptic team suggested that changes in Beatrice cannot be due to therapy; however, in her HAT forms she reported many therapeutic interventions that she considered useful, therefore changes in her are tied to those questions and sentences spoken by the therapist. About Beatrice's lack of sexual desire (item 6 of the PQ), the therapist did not work on that because the client had already attributed it to her infertility and consequently to her unsatisfying relationship. Moreover, the therapist did not work on her two specific performance/activity items (8 and 11 of the PQ) because Beatrice's suffering was tied to her incapacity to have biological children, and the therapist believed it was more important for Beatrice to work on her unheard and unmet needs and emotions correlated to her aspects of personality, and not directly on her symptomatology, and only afterwards, from session 12, focused on her incapacity to give birth and on her wish to be a mother even through adoption. Finally, Beatrice did not break up with her previous partner with the same modality she used with ex partners. In session 4, she stated that she spoke and explained him that she was unhappy "like a woman, like a mother, in this couple, with no plan, the cohabitation... we are different... I told him I was feeling like a second choice" (S4, L6-48), whereas in previous break-ups she "started the crisis, screaming, unhappy, mean... so after a while they would break up with me, and I've always ended up clean... I don't like this part of me" (S0B, L216-222). Finally, when the therapist suggested to Beatrice to reflect on her decision to leave her partner in session 16, she reflected and reported in the follow-ups to be still with her partner.

2. A decrease in the PHQ-9 score in the pre-treatment phase is inferior to the reliable change index, thus is not reliable and may reflect the error measure of the test.

3. Even if Beatrice started therapy with high levels of dependency, she did not act in a compliant way with the therapist. In fact, in session 2 the therapist made an early interpretation of her tendency to let others decide what she had to feel and think, just like her brother did with her when she was a little girl, and

Beatrice refuted it. Besides, if Beatrice had been compliant, her scores would have been in constant decrease, and not so fluctuating. Furthermore, there has been a break-up in the therapeutic alliance in session 7 when the therapist hypothesized that her feeling of making people who love her suffer, and her tendency to lie to prevent further sufferings, was generated from Beatrice's relationship with her mother when she was a little girl. In fact, in the following session (8), Beatrice explained to the therapist that in the previous session when she was criticizing her mother she left feeling guilty "because mom always did the best for me and I feel sorry talking like this about her, I'd want only to go and cuddle her in these moments" (S8, L187-189). Moreover, when the therapist rated the SWAP at the first follow-up, there were no more dependency traits in Beatrice (SWAP dependency PD-T score 51.8, and Q-T score 53.83), so for this reason a decrease in quantitative scores in the follow-ups is not tied to compliance and dependent traits.

4. We have no proof that Beatrice had any expectations from the therapy due to medical advice.

5. As previously stated, they started working on her incapacity of being a biological mother and on her possibility in the future to adopt a child only from session 12, when they decided together that the therapeutic contract had been unsatisfied. Beatrice needed first to get in touch with her emotions and needs and listen to them, which was her initial therapy contract, before working on her maternal loss.

6. When Beatrice referred to not being sure whether the changes in her life were likely due to therapy or not, she was talking about leaving her ex-partner and going to live on her own, and then she added "actually some changes depend on exchanging views with the therapist, because it gave me the opportunity to know myself better, to know my feelings and my desires better... for example, I understood that I took decisions based on strong emotions... and very impulsive decisions... without reflecting, instead I do reflect now" (CI, L54-61).

7. In the CI, Beatrice reported to have taken alprazolam before assessment session 0A, but having stopped straight after beginning therapy (CI, L31). Furthermore, in session 2, she stated that she kept it in her bedside table and to have taken it only when needed, and not very often (S2, L19-21). Also, there is no evidence of a rebound of insomnia after having quitted with the drug, a frequent collateral effect of benzodiazepines.

8. There is no evidence that Beatrice had been compliant to the research and to the therapist that conducted the CI for having worked for a short time as a researcher.

Sceptic Rebuttal

The sceptic team believes that Beatrice's quantitative changes are not due to therapy but to extra-therapeutic events. In fact, at the end of therapy quantitative scores rose corresponding to frequent fights and arguments she had with her partner, and PHQ-9, GAD-7 and CORE lost their reliable change. Just as in sessions 15 and 16, high scores at the beginning of therapy might correspond to fights with her previous partner about the wedding in which he wanted to participate and she did not, and about the holidays he wanted to spend with the family of his dead ex-girlfriend and she did not. For this reason, quantitative measurements might be unreliable. Regarding Beatrice's emotions, since session 12, when the therapist and the client decided to work on a new therapeutic contract, the score of item 4 ("I'm angry because life deprived me of the joy of being a mother") of the PQ increased, losing clinical significance. Furthermore, the client acted according to her strong emotions throughout the entire therapy by having fallen in love with the new partner. About Beatrice's dependence personality traits, she still acts according to her script behaviour, because she started the new relationship with her current partner with high idealization (changing house and city for him, marrying him), following high devaluation both of her needs (not feeling free to call her ex and have dinner with him) and of the partner (thinking of breaking up with him in session 16). Also, in the 1-month follow up, Beatrice reported that she was still together with her last partner, however, that she was acting according to her script, which is not breaking up with men even if she does not like how their current relationship has turned out to be: "he is happy that his son calls me 'mom', but this is wrong" (FU1, L90-91); "I don't want to do what I've done in the past, to drag... because this never led me to feel good" (L273-279). So, at the end of therapy and in the 6-month follow up, Beatrice reported to be still stuck in her script and desire to become a mother, without working on all her needs and wishes in a relationship. Finally, regarding the decreasing trendline that characterizes Beatrice's quantitative scores, improvements in the GAD-7 and CORE are reliable.

Affirmative Conclusion

Beatrice's depression, anxiety, global distress and personal problems were related to difficulties in emotions, self-esteem and interpersonal patterns, such as staying with a man even if their relationship was not satisfying for her anymore, not understanding nor listening to her needs and emotions and letting others decide them for her, acting and deciding according to strong, impulsive and not thoughtful emotions, and to finding out that she was not able to have biological children. She had a high level borderline functioning, structural problems, and

dependent personality traits. Since the beginning of therapy, the therapist created a positive climate where the client felt free to express and feel her emotions and problems, explored the possibility of appreciating her emotions, without having others tell her what was right for her. Beatrice's depression was also tied to her introjected characteristics, like introjecting blame and guilt into herself, and for her belief of always hurting people she loved and who loved her and, therefore not trusting her own perceptions. The therapist worked on adjusting guilt and on focusing on her emotions in order to understand and trust her feelings and wishes, which made Beatrice's symptoms decrease and allowed her to express and understand herself, instead of acting impulsively and retreating, increasing her self-esteem. There has also been a partial loss elaboration regarding her incapacity to give birth and, nevertheless, to the possibility to still be a mother through adoption. These experiences were reflected in changes in depressive symptoms, internal dialogues, acting out, self-identity and interpersonal relationships. The areas that have changed for the most are relationships, emotions and self-esteem.

Sceptic conclusion

Beatrice asked for therapy with moderate depression, which reached a reliable and subclinical symptomatology already in session 4 after having broken up with her partner, and might have been due to an adjustment disorder, so improvements might not be attributed to therapy. Changes in depressive symptoms are therefore likely to be due to a self-correction of the crisis for the alteration of her self-image, and extra-therapeutic events, such as finding a

man that gave her the attention she needed, that asked her to marry him, and that wanted to adopt a child with her. Therefore, quantitative improvement is unreliable and does not correspond to qualitative statements of the client in the follow ups.

Adjudication

Each judge examined the rich case record and hermeneutic analysis and compared their opinions reaching a consensus, reported in Table 5. The judges' overall conclusions are that this was a clearly good outcome case, that the client changed considerably and that these changes are considerably due to the therapy.

Opinions about the treatment outcome (good, mixed, poor)

This is a clearly good outcome (60% of certainty) with aspect of a mixed outcome (40% of certainty). Quantitative data show a reliable and clinically significant change on measures of depression (PHQ), anxiety (GAD) global distress (CORE) and personal problems (PQ) before the end of therapy, regained in the follow-ups. The spikes at the end of the therapy are representative of critical extra-therapeutic events, and not to the inefficacy of the therapeutic work. Also qualitative data support the conclusion that the client improved. Beatrice learnt to give voice to her emotions and desires, not allowing others (her ex and her current partner) decide them for her. Her internal representation on hyper-adjustment and having to be and behave like others wanted is not present anymore. She is able to protect herself from her partner's desires and decisions. Moreover, she learnt to not listen to her strong and impulsive emotions without reflecting first.

	Judges' consensus rating
How would you categorize this case?	Clearly good outcome
How certain are you?	60%
To what extent did the client change over the course of therapy?	60% Considerably
How certain are you?	80%
To what extent is this change due to therapy?	60% Considerably
How certain are you?	80%

Table 5: Adjudication results

Opinions about the degree of change

The client's change is considerable (60%, with 80% of certainty). Qualitative data, as in the session transcriptions, show both big changes in her life due to extra-therapeutic events, and a true improvement in Beatrice's impulsive acting outs. However, therapy has not been long enough to deeply explore and lead to a complete elaboration of her incapacity to give birth, which seemed to be still present at the end of therapy. Nevertheless, there is proof of a moderate change in her dealing with both her and others' emotions, she is able to protect herself from contaminations and give voice to her wishes and feelings, which allowed her to come out from that vicious cycle of hyper-adjustment.

Opinions about the causal role of the therapy in bringing the change

The observed change is considerably (60% with 80% of certainty) due to the therapy. Qualitative data in the HAT form (summarized in Table 3) of the client and the Change Interview are extremely helpful to understand what the client felt important in the course of therapy, such as the therapist interventions and questions that made her realize that she was hyper-adjusting to people, and that she was acting impulsively in the grip of strong emotions. Furthermore, qualitative data from the Change Interview report a retrospective attribution to therapy of four main changes out of five, especially improving her depressive and anxious symptoms (two changes), dealing with emotions and inner experience (two changes).

Mediator Factors

Good Therapeutic Alliance and therapist interventions on decontamination helped Beatrice to gain the awareness of her hyper-adjustment to others and of her actions that were based on strong emotions. The therapist worked on Beatrice's personality, on her tendency to introject blame and guilt, and to give others the permission to decide how she had to feel. Therefore, the therapist gave her the permission to recognize her emotions, listen to them, and decide on her own, without retreating.

Moderator Factors

Beatrice was a very intuitive, intelligent and introspective person, therefore therapist interventions led to very deep deep insights and to Beatrice's comprehension of having always acted according to ancient script belief.

Discussion

This case aimed to investigate the effectiveness of a manualized TA treatment for depression in a client with major depressive disorder in comorbidity with anxiety. Primary outcomes were depressive and anxiety symptomatology, and secondary outcomes were global distress and personal problems. The therapist conducted the treatment with good to excellent

adherence to the manual. The judges concluded that this is a clearly good outcome case, with a 60% degree of change, and which was 60% due to the therapy. These conclusions provide a further support for the effectiveness of the manualized TA treatment for depression in adults. Creating an early therapeutic alliance, supporting self-esteem, changing self-critical internal dialogues, developing an internal Nurturing Parent, providing appropriate permission tailored to the specific the needs of the client and developing problem-solving ability all appeared to be mediators of change in this case, which were moderated by the cognitive resources and self-observing attitude of the client.

Limitations

The first author has a strong allegiance to TA, is a teacher of the members of the hermeneutic groups and a colleague of the three judges. Despite the reflective attitude adopted in this work, these factors may have influenced in subtle ways both the hermeneutic analysis and the judges' evaluations.

Conclusion

This case study provides evidence that the specified manualized TA treatment for depression (Widdowson, 2016) has been effective in treating a major depressive disorder. Despite results from a case study being difficult to generalize, this study adds evidence to the growing body of research supporting the efficacy and effectiveness of TA psychotherapy, and notably supports the effectiveness of the manualized TA psychotherapy for depression applied to major depressive disorder.

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