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OUTCOME PREDICTORS IN COGNITIVE AND
BEHAVIORAL INTERVENTIONS

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NOTES

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(a) The thesis includes the original research work of Ramona Maria Moldovan (author) towards the Ph.D.; the research was scientifically supervised by Professor Daniel David, PhD
(b) Parts of the thesis have been already accepted for publication, or submitted for publication; appropriate citations for these publications were included in the thesis. Other co-authors have been included in the publications, if they contributed to the exposition of the published text, data collection or interpretation etc. (their contribution is clearly explained in the footnotes of the thesis);
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CHAPTER 1
THEORETICAL BACKGROUND

1. UNDERSTANDING HOW PSYCHOTHERAPY LEADS TO CHANGE

General perspective

A large body of research has established the efficacy and effectiveness of a range of psychological treatments. Meta-analyses and qualitative reviews have indicated that many forms of psychotherapy for children, adolescents, and adults lead to therapeutic change (e.g., Kazdin & Weisz, 1998; Lambert & Ogles, 2004; Nathan & Gorman, 2007, etc.) - research has repeatedly demonstrated that individuals with various clinical problems will, on average, benefit more from psychotherapy than from no treatment or a psychological control treatment (Cooper, 2008; Lambert & Ogles, 2004). The changes have been most often shown to include social, emotional, cognitive, behavioral, educational, and physical areas of functioning.

We do know that therapy "works" (i.e., is responsible for change) but still have rather little knowledge of how it works (Kazdin, 2007). Understanding and promoting effective treatment is best accomplished by understanding the 'mechanisms' of action that cumulatively result in positive outcomes, thus clarify what exactly in the process of psychotherapy is responsive for change (Kazdin, 2007; 2009). Determining the means by which effective psychotherapy works is critical: identifying the essential "ingredients" and the mechanisms through which treatments work is essential for maximizing treatment efficacy, improving therapeutic techniques, and improving methods for training therapists (Kazdin & Nock, 2003; Weersing & Weisz, 2002). Despite the importance of this area of research, there is a significant gap between our knowledge of treatment outcomes and the processes associated with those.

Central to this paper is the thesis that, with isolated exceptions, we do not know why therapies achieve therapeutic change, the requisite research to answer this question is rarely done, and new as well as innovative approaches are needed in conceptualization and research design (Kazdin, 2009).

Relevance of the field

Despite the proliferation of different theories and numerous investigations demonstrating the overall efficacy of many psychological treatments, the field still has rather few firm answers about how psychotherapy leads to change (e.g., Kazdin, 1998; Kopta, Lueger, Saunders, & Howard, 1999).

Understanding mechanisms can help to bring order and parsimony to the current status of treatments. Many different psychological interventions exist and define themselves as being rather distinct; however, treatment packages actually share common components or procedures (e.g., Ablon and Jones, 1999). Moreover, it has been argued that elements that are common among different approaches account for more change than do those that are unique to different approaches (Wampold, 2001). Identifying the mechanisms through which people change in treatment will provide the data necessary to clarify what are the common and specific factors responsible for clinical change (Nock, 2007).

Researchers and practitioners both agree on the importance of understanding the nature and causes of change in psychotherapy; however there is little agreement as to what constitutes even an examination of change. One common focus of change studies is attempts to identify the ''active ingredients'' in therapies (Haaga & Stiles, 2000; Hollon, Evans, & DeRubeis, 1990). Studies in this vein seek to examine aspects of the therapy (e.g., therapist interventions or specific techniques) that affect therapy outcomes. Another common vein of

change studies involves the amount of change in client variables (e.g., social or communication skills, or maladaptive or anxious cognitions) created by therapy, and the relation of those changes to the ultimate outcome of therapy (e.g., reductions in depressive symptoms; Hollon et al., 1980; Whisman & Snyder, 1997).

As the field moves toward identifying empirically supported treatments for mental disorders, it becomes more and more important to not only identify specific treatment packages that are effective for specific disorders (essential for making decisions about the best treatment choice today) but also validate the theoretically relevant mechanisms of change of these efficacious treatments in order to provide the best opportunity for further improving the effects of treatments currently available (Gibbons, 2009).

Current state of the literature

Despite a recent surge of interest in the mechanisms and processes of change during psychotherapy, investigations to date have yielded very few interpretable results (Doss, 2004). While some treatment models have clearly articulated mechanisms, others focus on broad principles without a clear understanding of how they work. We will briefly discuss some of the most often investigated factors responsible for change in the therapeutic process.

Mechanisms of change and Mediators. An excellent review of mediators of treatment outcome (Johansson & Hoglend, 2007) identified 61 published psychotherapy studies where some form of mediational analysis has been carried out. We further present some of the most compelling findings. Findings are not consistent across studies (DeRubeis et al., 1990; Kolko et al., 2000; Wilson, Fairburn, Agras, Walsh, & Kraemer, 2002; Hofman, 2004; Smits, Powers, Cho, & Telch, 2004; Kaufman, Rohde, Seeley, Clarke, & Stice, 2005): results show both that no variables were found to mediate the impact of psychotherapy and that various cognitions mediate the impact of psychologycal interventions on symptoms.

Psychotherapist/Client characteristics and Moderators. The therapists' contribution to outcome in therapy has been the focus of considerable interest particularly since the establishment of a number of empirically supported psychological interventions for a variety of disorders (Huppert et al., 2001). Several issues have been addressed under the rubric of therapist variables or therapist factors that influence outcome in psychotherapy. Researchers have conducted analyses evaluating what specific factors or variables contribute to differences in therapists' outcome. Such factors include demographic characteristics (e.g. age, gender, race, and religion), training characteristics (e.g. degree, training, years of experience, and number of patients), personality characteristics, and theoretical orientation (Huppert et al., 2001). Empirical data are not substantial when it comes to clarifying therapist variables that are responsible of the outcome in therapy - a recent and comprehensive review (Elkin et al., 2006) concludes that there are virtually no significant findings in regard to either overall effects of therapists or the interaction with patient severity and difficulty. Therapists' experience, competence, adherence and allegiance are hypothesized to be important variables in predicting psychotherapy outcome but still need additional empirical support in order to advance firmer conclusions. When looking at client characteristics that best predict treatment outcome, expectations and working alliance have garnered the most empirical support.

1.   FUNDAMENTALS OF COGNITIVE BEHAVIORAL THERAPY

General remarks

The etiology of emotional disorders is far from being completely understood. In many cases, emotional disorders are triggered by stressful life events, yet not everyone becomes disturbed under negative circumstances. Over the last few decades, the role of cognitions as

maintaining, predisposing or causal factor in various emotional disorders has captured the interest of the scientific community, resulting in a proliferation of publications and the development of treatment approaches designed to alter cognitive contents or processes hypothesized to be etiopathogenetic (Szentagotai et al., 2008). There is evidence that cognitive-behavioral approaches (e.g., see the American Psychological Association's list of empirically validated treatments at www.apa.org) are among the best empirically supported, both in terms of theory and intervention.

Cognitive Behavioral Therapy (CBT) is an approach that has a central focus on the way individuals interpret events. States of emotional disturbance are seen as emerging from problematic, maladaptive, and/or unrealistic interpretations (Kellogg & Young, 2008). Most cognitive-behavioral therapies are based on Albert Ellis' ABC model of distress (Ellis, 1962; 1994), more precisely, on its main idea that beliefs (B) mediate the impact of different activating events (A) on various emotional and behavioral consequences (C). According to this model, people experience undesirable activating events (A), about which they have distorted (irrational dysfunctional) or undistorted (rational/functional) beliefs/cognitions (B) of themselves, the world, and the future. These beliefs then lead to dysfunctional or functional emotional, behavioral, and cognitive consequences (C). However, in their attempt to explain emotional disorders, various professionals have ascribed greater importance to particular types of cognition, resulting in the creation of several theoretical models of these crucial types of cognitions (David & Szentagotai, 2006). Two of the most influential and widespread forms of CBT are Rational Emotive Behavioral Therapy (REBT) and Cognitive Therapy (CT).

Rational Emotive and Behavioral Therapy (REBT) is the oldest form of cognitive-behavioral therapy (CBT) and was created by Albert Ellis more than five decades ago. REBT is based on the premise that human psychological problems are rooted in irrational beliefs (Ellis, 1962; 1994). The "ABCDE" model is emblematic for REBT (Ellis, 1994). According to the "ABCDE" model, people experience undesirable activating events (A), about which they have rational and irrational beliefs (B). These beliefs lead to emotional, behavioral, and cognitive consequences (C). Rational beliefs (RBs) lead to functional consequences, while irrational beliefs (IBs) lead to dysfunctional consequences (David et al., 2008). Clients who engage in REBT are encouraged to actively dispute (i.e., restructure) (D) their IBs and to assimilate more efficient (E), adaptive and rational beliefs, with a positive impact on their emotional, cognitive, and behavioral responses (Ellis, 1994; Szentagotai et al., 2005; David & Szentagotai, 2006). Irrational beliefs are typically described as evaluative beliefs (i.e., hot cognitions or appraisal) rather than distorted descriptions and/or inferences (i.e., cold cognitions) (see David & Szentagotai, 2006 for details).

Irrational beliefs fall into four categories of irrational (dysfunctional/maladaptive) cognitive processes (Szentagotai et al., 2005; Ellis et al., 2010) mainly described as non-pragmatic, absolutistic, inconsistent with reality and rigid (David et al., 2005): (1) Demandigness (DEM). DEM is viewed as the core irrational belief and it refers to absolutistic requirements expressed in the form of "musts", "shoulds" and "oughts" that indicate imperative or absolutistic demands on self, others, and life. The rational correspondents of demands are full preferences, which are flexible assertions of what the person wants; (2) Awfulizing/catastrophizing (AWF). AWF refers to one evaluating a situation as worse than it absolutely should/could be while a rational, non-awfulizing belief refers to a more moderate evaluation of badness (i.e., bad rather than awful); (3) Global evaluation/Self downing (GE/SD). GE/SD is present when individuals tend to be excessively critical of themselves (i.e., to make global negative evaluations of themselves) and also of others and life conditions. The rational counterpart of global evaluation is unconditional self,

other and world acceptance, while only rating specific behaviors; (4) Low Frustration Tolerance (LFT). LFT refers to the individuals' belief that they cannot endure, or envision being able to endure a given situation. High frustration tolerance beliefs on the other hand, assert that although a certain situation is hard to bear, it is not intolerable.

These four irrational cognitive processes cover various areas of content (e.g., performance, comfort, affiliation) and refer to ourselves, others, and life conditions (Ellis et al., 2010). According to Ellis (1962; 1994), DEM is the core irrational belief, and all other irrational beliefs are derived from it.

According to the *Cognitive Therapy (CT)* theory, as hypothesized by Beck (1976), people have relatively stable cognitive patterns (i.e., core beliefs encoded as schemas) that develop as a consequence of early learning and that lead them to make negative and distorted interpretations of specific life events (i.e., automatic thoughts). The relation between core beliefs and automatic thoughts is mediated by intermediate beliefs such as attitudes, assumptions, and rules (see Beck, 1995 for details). Automatic thoughts are typically described as distorted descriptions and/or inferences (i.e., cold cognitions) rather than evaluations/appraisals (i.e., hot cognitions) (David & Szentagotai, 2006).

Beck (Beck, 1987; Bedrosian & Beck, 1980) has outlined a number of processes (for a recent and comprehensive review see Kellogg & Young, 2008):

• *Arbitrary inference:* Coming to a conclusion that is either not supported by existing evidence or is actually in defiance of it.

• *Selective abstraction:* Conceptualizing a situation based on a detail; however, the bigger picture is not taken into consideration so that the conclusion is out of context.

• *Overgeneralization:* Creating a rule that is based on a few specific instances, which is then applied to many other situations, even those for which it is not appropriate. Patients may also make global judgments about themselves based on a few (or even one) incidents.

• *Magnification or minimization:* Seeing things as either more or less important than they really are. This distortion is so extreme that it is detrimental to the individual.

• *Personalization:* Attributing the cause of outside events to yourself even when there is no evidence that this is the case.

• *Dichotomous (or polarized) thinking:* Interpreting things in terms of extremes. Events are classified as either totally good or totally bad; there is no middle ground.

• *Incorrect assessments regarding danger versus safety:* Sensing risk as disproportionately high. This distortion is commonly found in anxiety disorder patients, and the result is that they live lives of fear and restriction.

The rationale for change in CT is based on similar principles as the rationale in REBT. Specifically, changes of these distorted beliefs are followed by changes in symptoms.

Current state of the literature

A central theoretical principle guiding CBT is that addressing cognitive processes is linked to successful treatment. This mediation hypothesis can be broadly defined as encompassing two related questions (Garratt et al., 2007): "are cognitive changes associated with therapeutic improvement?" and "are changes in cognition specific to cognitive therapy?" These questions are particularly important when CBT is compared to other treatments (i.e. pharmacotherapy).

In both CT and REBT approaches, the therapist focuses on changing dysfunctional/irrational cognitions and on remedying associated emotional and/or behavioral consequences (David & Szentagotai, 2006). The main difference between the two theories of change is that REBT, compared to CT, has a special focus placed on identifying and restructuring evaluative cognitions, rather than non-evaluative cognitions.

The first review in the clinical literature addressing this very specific topic was conducted by Weersing and Weisz (2002) and found that CBT did produce consistent change reflected in overall treatment outcomes for both anxiety and depression. They reported that CBT was associated with change in cognitive mediators in all anxiety studies, and CBT was associated with change in cognitive and behavioral mediators in most depression studies. However, no specific effect sizes were provided to indicate the relative strength of these associations.

Three additional reviews explored similar issues. Prins and Ollendick (2003) reviewed the evidence for cognitive and coping variables as mediators of CBT for anxious youth. Similar to previous reviews, they found few studies testing for mediation but many assessed pre to post-treatment outcomes of cognitive or coping process. Of those studies that did measure process variables, CBT demonstrated consistent effects. The authors note that, when comparing CBT to an alternate active treatment, CBT produced significant pre- to post-changes in cognitive and coping processes, but these differences were not significantly different from the control conditions. Thus, CBT may be associated with cognitive changes, but such change may not be uniquely related to CBT.

Davis and Ollendick (2005) conducted a comprehensive review of CBT in producing specific change in a broader set of processes associated with specific phobia, including cognitive, behavioral, physiological, and subjective fear. Their review included 22 clinical trials that compared a behavioral or cognitive treatment to either an active or passive control condition. There was significant evidence that behavioral treatments produced positive change in most behavioral and fear measures. This finding held whether compared to either passive or active controls. Thus, behavior and subjective fear appear to be both reliably produced by, and specific to, behavioral treatments in the treatment of specific phobias.

A third research conducted a meta-analysis evaluating the overall outcomes of CBT for anxious and depressed youth when compared against either a bona fide (active psychological treatment with a defined theory) or non-bona fide (nonspecific active control) therapy (Spielmans et al. 2007). They divided outcome measures into dependent variables that either directly measured anxiety or depression or measured some other outcome of interest. Their analysis suggested that CBT did produce significant treatment effects in both anxiety- and depression-specific and more general outcomes when compared to active controls. However, the analyses did not divide the anxiety and depression measures into specific component processes of cognitive, behavioral, coping, or physiological outcomes.

The most recent review investigating candidate mediators of change in CBT for Anxious and Depressed Youth was conducted by Chu & Harrison (2007). Their study provides one of the most comprehensive reviews to date of specific effects of CBT for anxious and depressed youth. It also provides evidence for potentially differentiating mechanisms in the treatment of anxiety and depression. Consistent with cognitive-behavioral theory, CBT for anxious youth produced consistent moderate to large effects across process variables, with the largest effect found for behavioral outcomes - CBT appears to have a consistent impact in both specific and general measures of cognition.

2.   [1]INTEGRATING THE PSYCHOTHERAPEUTIC PROCESS INTO A METHODOLOGICAL FRAMEWORK

We now know well that psychotherapy works (i.e., is responsible for change) but still have rather little knowledge of for whom, under what conditions and how psychotherapeutic treatments work (Kazdin, 2007) as most studies continue to focus on gathering empirical data to support various (psycho)therapeutic packages while ignoring whether there is any evidence to support the proposed theoretical underpinnings of these techniques (David, 2004); the means through which these therapies exert their beneficial effects are generally not well understood (Kazdin, 2009; Webb et al., 2010) as investigations to date have yielded very few interpretable results (Doss, 2004). As a matter of fact, it is quite remarkable that after decades of psychotherapy research, with isolated exceptions, we cannot provide an evidence-based explanation for why even our most well studied interventions produce change (Kazdin, 2007). Certainly, all psychological interventions are based on theories that explain why improvements supposedly occur (some of them have clearly articulated mechanisms while others tend to be more focused on broad principles), but these theoretical assumptions are rarely put to the test empirically (Johansson & Høglend, 2007).

Mechanisms of change versus other related concepts: theoretical delimitations
Given the inconsistencies that have been used when discussing mechanisms of change, it is important to clarify key concepts as well as describe how they relate to each other and how they fit into the broader scientific context (Nock, 2007). Several interrelated and overlapping concepts are important to distinguish: A *mechanism* of change refers to the process or series of events through which one variable leads to and/or causes change in another variable. Mechanisms of change reflect the processes through which some independent variable (i.e. therapy) actually produces the change and explain how the intervention eventually leads to the outcome (Kazdin, 2007). Generally, in psychotherapy research, the goal is to understand the mechanisms of change; the study of mediators is most often the means to achieve this aim. A *mediator* is a construct that shows specific statistical relations between an intervention and the outcome. Mediators of treatment effects are variables which account for, in a statistical sense, at least some of the effects of treatment on the outcome (Baron & Kenny, 1986). Mediational analysis allows the clarification of how treatments have effects and, particularly, what are the possible mechanisms through which a treatment might achieve its effects (Kraemer et al., 2002). The mediator is potentially a mechanism through which the change occurs (Johansson & Hoglend, 2007). This suggests that treatment causes the mediator variable to change, which then leads to the outcome. In psychotherapy, mediators are typically processes within the patient (e.g. cognitions, abilities or functioning etc.). A *moderator* refers to some characteristic that influences the direction or magnitude of the relation between the intervention and the outcome. Generally speaking, moderators clarify for whom or under what conditions an intervention works (Baron & Kenny, 1986). If treatment outcome varies as a function of different characteristics of the patient (e.g. age, symptoms, expectations), therapist (e.g., sex, experience, self-efficacy) or treatment delivery (e.g., individual versus group treatment), these latter variables are moderators (Kazdin, 2007). To show that a variable is a moderator of treatment the variable must be a baseline or pre randomization characteristic (in other words, it precedes treatment); second, the variable must be uncorrelated with treatment; third, the variable has to be shown

to have an interactive effect with treatment on the outcome, that is "explain", in a statistical sense, individual differences in the treatment effects (Kraemer et al., 2002).

Clearly, the mediator is proximal to the mechanism of change and also necessary for demonstrating mechanisms of change; in the following section we concentrate on several methodological and statistical aspects related to mediation testing in randomized clinical trials.

Investigating mechanisms of change. Demonstrating mediators

Over the past 2 decades, researchers have developed several methods for testing whether a proposed mechanism can act as a mediator, in other words statistically explain the relationship between an independent and a dependent variable. Theoretically, to show that a variable is a mediator of a treatment, that variable would have to measure an event or change occurring during treatment, and then it must correlate with treatment choice, hence possibly be a result of treatment, and have either a main or interactive effect on the outcome (Kraemer et al., 2002). The directionality of mediation is unambiguous since mediators are not defined statistically but theoretical models are being used in order to define putative mediators and statistics are being used to evaluate a presumed mediational model.

Practically, to show such a relation, one must demonstrate that an independent variable (A) is associated with a dependent variable (B); that A is associated with the proposed mechanism (M); that M is associated with B; and when A and M are both covaried with B, M continues to be associated with B but the relationship between A and B is diminished. This pattern of relationships provides evidence that A is associated with B through its relation with M (Nock, 2007; Baron and Kenny, 1986; MacKinnon et al., 2002).

Statistical evaluation can play a central role in addressing whether a particular construct accounts for change. A variety of procedural/statistical solutions have been developed to assess whether a putative mediator meets statistical criteria for mediation, each one with its own advantages and limits: *The difference scores solution, The residualised change solution, The ANCOVA solution, The autoregressive model solution and The Latent Growth Curve (LGC) Model solution.* For a comprehensive review addressing the limits of cross-sectional mediation procedures when applied to longitudinal data several comprehensive works are available (MacKinnon, 2007; Cole & Maxwell, 2003, Gollob & Reichardt, 1985).

CHAPTER 2
METHODOLOGICAL STRATEGY

Patients come into therapy (as individuals, couples, or families) with certain behavioral, emotional, physiological and/or cognitive difficulties, and they seek relief from these problems by the time therapy is completed. In most cases, their needs are granted. Psychotherapy works. The ambition to understand how psychotherapy works has been guided theorists, researchers, and practitioners in psychotherapy for decades. This has led to an accumulation of literature, both theoretical and empirical, regarding the factors that lead to change in the psychotherapeutic process. A large body of research has established the efficacy and effectiveness of a range of psychological treatments but little is known about how they work; an important task is to identify principles and processes of change. Knowing not only whether psychotherapeutic treatments work, but also for whom, under what conditions they work and how they work, can guide future development of treatment theory and practice and may have serious impact on therapy training policies. We do know that not all patients benefit from psychotherapy; therefore, uncovering mechanisms of action might

enhance our understanding of differential responses to treatment and also help to maximize improvement in patients.

Theory and research in this area have been less focused on developing a systematic approach to understanding predictors of outcome in psychotherapy. Being aware of what implications psychotherapy has and will have even more in the future, the current research, although modest in the context of a vast scientific arena, aims to take a step toward a cohesive approach of predictors of outcome (common and specific) in psychotherapy research.

The first two studies are mainly concerned with specific factors in cognitive and behavioral psychotherapies: Study 1 is a quantitative meta-analysis investigating mediators in cognitive-behavioral psychological interventions which are then empirically investigated in Study 2. Studies 3, 4 and 5 are focused on common factors within psychotherapy; specifically, the predictors of outcome investigated here are working alliance, therapists' performance, patients' expectations, therapists' allegiance, therapists' self-efficacy and unconditional self-acceptance. Study 6 is aimed at investigating the shape of change over the course of therapy and, based on formulas derived from empirical data, to develop a software program that not only will track changes but will also predict estimated progress and give feedback

CHAPTER 3
ORIGINAL RESEARCH

[2]STUDY 1. MEDIATORS OF OUTCOME IN COGNITIVE-BEHAVIORAL PSYCHOLOGICAL INTERVENTIONS. A QUANTITATIVE METAANALYSIS

Cognitive Behavioral Approach and Theory of Change

CBT is one of the most extensively researched forms of psychotherapy and has received significant empirical support with hundreds of clinical trials and outcome studies being published over the last decades. Yet, many questions remain regarding the overall effectiveness of CBT (Butler et al., 2006). Reviews of the mechanisms of change in CBT outcomes are therefore particularly relevant by addressing this challenge and by adding value to previous work in this area.

Knowing the mechanisms that makes CBT effective could add significant value to previous work in this area and guide the development of more effective intervention protocols, designed to modify specific variables that best explain variations in outcomes. Our approach is unique in that we systematically summarize findings across randomized clinical trials focusing on specific cognitive variables mediating the impact of CBT (as a whole) on the outcome and estimate their effect size.

Methodological and statistical issues in the study of change process in psychotherapy

Identifying and examining mediators of treatment change has proven to be essential as it can elucidate the ways in which psychotherapy has effects on outcomes. The identification of mediators is an initial step in establishing how treatments work, the next step being the testing of the causal status of any identified mediators by manipulating them. Therefore, identifying mediators is especially valuable in narrowing down the search for causal mechanisms (Murphy et al., 2009).

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[2] This study has been submitted for publication in *Psychotherapy*

The current study
In trying to understand the mechanisms through which CBT works, the aim of the current study is to identify and assess the impact of mechanisms that have been found to mediate the effect of CBT on the outcome. There are a number of studies investigating the impact of various mediators on the outcome (Crits-Christoph et al., 2003; Kaufman et al, 2005; Beauchaine et al., 2005). Also, there are several important papers exploring the evidence for cognitive variables as mediators of CBT for various disorders or age groups (Davis & Ollendick, 2005; Prins & Ollendick, 2003; Chu & Harrison, 2007). Having said that, no meta-analysis has been conducted so far to investigate specific cognitive variables mediating the impact of CBT (as a whole) on the outcome and to estimate their effect sizes. The main objective of the study was to carry out such an analysis; specifically, we aimed to estimate the overall effect size of various mediators in CBT.

Method

Literature review
An extensive electronic search was conducted of the literature published until April 2009, without a specific starting point. Studies included in the sample were identified through a computer search of the MEDLINE and PSYCINFO databases. The following keywords were used to conduct the literature search: *cognitive therapy and mediators, cognitive therapy and mediation, cognitive behavioral therapy and mediators, cognitive behavioral therapy and mediation, cognitive therapy and mechanisms of change, cognitive behavioral therapy and mechanisms of change, cognitive therapy and theory of change, cognitive behavioral therapy and theory of change.* As an additional search method, we reviewed the reference list of all the reviews found.

Inclusion / Exclusion Criteria for Study Selection
The initial search resulted in 593 articles. Initial inclusion criteria were: (1) a randomized clinical trial investigating the role or mechanisms of cognitive behavioral-based interventions; (2) a clearly defined cognitive behavioral-based intervention; (3) the existence of a control group; (4) sufficient data reported to allow calculation of effect sizes; (5) a clear mediation analysis of one or several variables on the outcome; (6) the study was published in English, in a peer-reviewed journal.

We excluded experimental studies and clinical trials with no control group – wait list, placebo and pharmacotherapy were the only control conditions accepted. Given our focus on mediators of outcome in CBT, studies aiming to investigate mediators but failing to perform mediation or to identify mediators (either because of lack of correlation among variables or because of insigniffficant parameters) were also excluded (Szentagotai et al., 2008). Three randomized clinical trials who identified a mediation efect but failed to report sufficient data to allow calculation of effect sizes were also excluded.

Based on the criteria mentioned above, 11 studies were identified for inclusion. Table 1 presents a summary of these studies and their characteristics, including sample size, type of disorder, type of treatment and control, number of sessions in treatment, outcome measures and mediators identified.

Table 1. Summary of studies included in the meta-analysis

Study	Participants (N), Age	Treatment group	Control group	CBT type	Sessions	Disorder	Outcome	Assessment
Ackerson et al., 1998	22 (M = 16, SD = 1.4)	CBT	Wait list	Individual	4	Moderate Depression	Depression symptoms	Baseline, End of treatment, 4 weeks Follow-up
Blalock et al., 2007	517 (M = 44.8, SD = 9.9)	CBASP	Pharmacotherapy	Individual	16	Chronic depression	Depression symptoms	Baseline, End of treatment
DeRubeis et al, 1990	64 (M = 33, SD = SD = 7.3)	CBT	Pharmacotherapy	Individual	20	Major depression	Depression symptoms	Baseline, Week 6, End of treatment
Hofmann, 2004	90 (M = 31.05, SD = 9.2)	CBT	Wait list	Group	12	Social phobia	Social anxiety	Baseline, End of treatment, 6 months Follow-up
Hofmann et al., 2007	91 (M = ,37.56 SD = 10.54)	CBT	Pharmacotherapy	Individual	11	Panic	Panic symptoms	Baseline, End of treatment, 6 months Follow-up
Kaufman et al., 2005	93 (M = 15.1, SD = 1.4)	CBT	Life skills	Group	16	Major depression	Depression symptoms	Baseline, End of treatment, 6 and 12 months Follow-up
Kendall & Treadwell 2007	145 (M = 11, SD = 1)	CBT	Wait list	Individual	Unknown	Anxiety Disorders	Anxiety, Fear	Baseline, End of treatment
Quilty et al., 2008	130 (M = 42.57, SD = 11.71)	CBT	Pharmacotherapy	Unknown	18	Major depression	Depression symptoms	Baseline, End of treatment
Smeets et al., 2006	211 (M = 31.24 SD = 7.8)	CBT	Wait list	Individual	17	Chronic Low Back Pain	Disability, Complaints, Pain	Baseline, End of treatment
Smits et al., 2004	130 (M = 33.93, SD = 9.32)	CBT	Wait list	Group	12	Panic	Panic symptoms	Baseline, End of treatment
Spinhoven et al., 2004	148 (M = 39.8, SD = 9.1)	CBSST	Wait list	Group	29	Chronic Low Back Pain	Depression, Pain behaviors, Activity tolerance	Baseline1, Baseline 2, Week 4, After 10 weeks of treatment, 6 and 12 months Follow-up

Study coding procedures

Studies were coded to identify (a) sample size; (b) diagnosis; (c) treatment and design characteristics; and (d) mediators identified. Coding was performed independently by three experts (licensed clinical psychologists and supervisors in CBT), and interrater agreement was 100%. Treatment outcome measures were included for ES coding if they assessed symptoms (emotions, behaviors), general functioning and improvement. Mediator measures were included if they assessed cognitive, behavioral or coping constructs (e.g., dysfunctional cognitions, irrational beliefs).

Statistical Analyses

Effect size (ES) parameters as well as pre- and post- means, pre- and post-standard deviations, and sample sizes for all conditions in each study were included. Cohen's *d* (Cohen, 1988) was used as a measure of ES.

ES were calculated according to published procedures. Cohen's d is the mean difference between the mean outcome in the treatment group and the mean outcome in the control group divided by the pooled (within-group) standard deviation. When data were not presented in this format, we transformed them into Cohen's d to compute the ES. To interpret ES, we used Cohen's (1992) definitions according to which an ES of 0.20 indicates a small effect, 0.50 a medium effect, and 0.80 a large effect.

All ES values were corrected for small sample bias (Hedges & Olkin, 1985), computing D instead of d and variance of D - VAR D instead of SD of d (Hunter & Schmidt, 1990). ES values were then weighted by the inverse of their variance, adjusting for varying sample sizes and heterogeneity of variance across studies (Hedges & Olkin, 1985).

When calculating mean ES values, a Q statistic was calculated to test whether all ES values estimated the same population (Lipsey & Wilson 2001). If homogeneity is rejected, this indicates that the variability among the study effect sizes is greater than what is likely to have resulted from subject-level sampling error alone. In our case, $Q(28) = 72.74$, $p < .05$. In addition to Q, the $I2$ index was computed in order to verify the extent of the heterogeneity: $I2 = 60\%$ CI: 42.17 and 77.83. As the confidence interval does not include 0%, there is evidence for true heterogeneity (Higgins & Thompson, 2002; Higgins et al., 2003). Thus, we adopteded a random effects model which accounts for random variability at both study-level (studies sampled from a population of studies) and subject-level (subjects in each study sampled from a population of studies).

To estimate the overall ES of mediators on the outcome the 95% confidence interval for the effect size was calculated and then compared to zero. Q-between was used to investigate whether various categories of mediators differed from each other in terms of ES.

Results

Descriptive Characteristics of Reviewed Studies

The final sample consisted of 11 randomized clinical trials investigating mediators of change in CBT. Where CBT was not explicitly described (Blalock et al., 2007; Spinhoven et al., 2004), the authors' definition of the intervention was analyzed. Cognitive Behavioral Analysis System of Psychotherapy (CBASP) and Cognitive Behavioral and Social Skills Training (CBSST) were considered CBT-based interventions as they were defined as combining behavioral, cognitive, and interpersonal problem-solving procedures, targeting global, problematic cognitions, and maladaptive behaviors

that interfere with attaining situational goals in interpersonal situations (Blalock et al., 2007). These principles underpin the theory and practice of CBT as well. Of the 11 studies, six used a wait list control, four compared CBT to pharmacotherapy and one study used a life skills condition. CBT was delivered in group or individually. Participants in these studies were adolescents and adults with depressive disorders (five studies), anxiety disorders (four studies) or pain (two studies). All studies reported assessment measures used to assess mainly global indicators of depressive, anxious or pain symptoms prior to or post treatment; a diverse range of methods were used to assess cognitive processes. No direct objective measures were used. Self-report was the primary mode of assessment in all studies. Follow up measures were heterogeneous, ranging from 4 to 10 weeks and 6 to 12 months. Descriptive information about study design, participants and treatments is reported in Table 1.

Mediator analyses

Our analyses revealed 29 cognitive mediators with ES ranging from $d = 0.06$ (no effect) to $d = 1.64$ (high effect). Our analysis indicated a significant global mediation effect of cognitions on outcome. Data indicate a low to medium ES ($D = .42$) of cognitive mediators on the outcome, at post treatment. Ninety-five percent CI indicates that this ES significantly differs from zero [(CI = .40, .50) $p < .05$]. The number of patients was 1,876 and the number of ES was 29.

Based on a review of the literature and on the references indicated by the authors of the studies included in the analyses (particularly references dealing with the measures used in the studies), all mediators identified were grouped into the following categories: (1) automatic thoughts; (2) anxious self-statements; (3) attributional style; (4) catastrophizing; (5) coping; (6) estimated social cost; (7) dysfunctional attitudes; (8) fear of fear; and (9) hopelessness. As Table 2 indicates, various types of mediators have a low to medium ES on the outcome.

Table 2. Effect sizes of mediators (total N = 29)

Mediators	Size effect
coping (N = 2)	D = **.14** [(CI = .01, .27) p <.05]
attributional style (N = 2)	D = **.22** [(CI = .21, .23) p < .05]
anxious self-statements (N = 3)	D = **.40** [(CI = .32, .66) p < .05]
fear of fear (N = 4)	D = **.47** [(CI = .46, .48) p < .05]
dysfunctional attitudes (N = 4)	D = **.50** [(CI = .29, .71) p < .05]
catastrophizing (N = 10)	D = **.53** [(CI = .40, .63) p < .05]
estimated social cost (N = 1)	D = **.78** CI = no value
hopelessness (N = 1)	D = **.88** CI = no value
automatic thoughts (N = 2)	D = **1.15** [(CI = .86, 1.44) p < 05]

Coping seems to have the lowest ES. Attributional style, anxious self-statements, fear of fear and dysfunctional attitudes have a low effect. Catastrophizing and estimated social cost have a medium effect, while hopelessness and automatic thoughts have a high effect.

Our second objective was to compare ES by the nature of mediators. Given the fact that all mediators identified were cognitions and having extensively reviewed the literature, we classified the mediators identified into two categories: evaluative and non-evaluative cognitions. Again, three experts in clinical psychology, affective disorders and cognitive-behavioral therapies grouped the mediators into the two categories with a final agreement between them of 100%. Cognitive mediators were included in each of the two categories as follows: (1) Evaluative cognitions: catastrophizing, estimated social cost; (2) Non-evaluative cognitions: dysfunctional attitudes, attributional style, coping, automatic thoughts, anxious self-statements, fear of fear.

Effect sizes computed for these two categories indicated a higher effect of evaluative cognitions [D = .55, (CI = .40, .60) p < .05] when compared to non-evaluative cognitions [D = .39, (CI = .34, .66) p < .05]. Although relevant from a theoretical point of view, differences are not significant from a statistical point of view [$F(1, 27) = 2.07$, p = .16].

Conclusions and discussion

Our analysis revealed a significant mediation effect of cognitions on the outcome. This global indicator may be very meaningful, particularly in this early phase of research in the area, both from a theoretical and a practical point of view. Cognitive mechanisms seem to be responsible, to some extent, for depressive, anxious and pain symptoms; data suggest that cognitive mechanisms play an important role in modifying some of these symptoms. Even though this indicator has a low to medium effect and explains only 4% of the outcome variance, it does suggest a cognitive mediation of symptoms and, consequently, of outcome results. These results also indicate that there are several other factors influencing the outcome – these factors may be specific to CBT or, most likely, they may be non-specific factors, that is factors influencing outcome in other psychosocial interventions as well. Such factors could refer to working alliance, patient characteristics or placebo (Lambert, 2003).

Interestingly, non-evaluative cognitions have a low but significant effect on the outcome; specifically, they explain 3% of the outcome variance. Evaluative cognitions have a medium and significant effect on the outcome – they explain 8% of the outcome variance. Although there are no significant differences between evaluative and non-evaluative cognitions, in term of effect, the direction of the differences is consonant with previous literature.

There are several limitations to the current review. As in any meta-analysis, results are limited to the studies included in the analyses. Our inclusion criteria allowed the analysis of only few rigorous studies; these strict criteria eliminated several prominent RCTs in the CBT literature (e.g. Jacobson et al., 1996). Another limitation worth mentioning is that, given the lack of assessments performed during treatment and at follow up in most RCTs investigated, mediations analyses should be regarded with caution: a larger number of assessments (both in terms of mediators and outcome descriptors) would have provided a more valid picture of the change process. Last, the heterogeneity of the studies included in the analyses (in terms of treatment, disorders, mediators, measures) also compels a cautious interpretation of our results. Another

limitation is the possibility of a publication bias which, although to a great extent characteristic of this field of research rather than this meta-analysis alone, may have contributed to our conclusions. Thus, it is more likely to find studies where positive results are reported rather than negative or inconclusive results; in this particular case, it is possible that authors were more likely to report mediation analyses where results were significant rather than results where mediation could not be tested or results were not significant. In order to evaluate the stability of our results, fail save N was calculated (Hunter & Schmidt, 1990). The number of new, unpublished or non-significant studies that would be required in order for our results to be non-significant is 35.2. In addition, we also investigated the publication bias using an algorithm derived from Stauffer's method ($X = (\Sigma zi)^2/2706\text{-NL}$ in relation to a critical level of 5NL+10, where NL is the number of studies in the meta-analysis) (Rosenthal, 1979). Data indicated that it is unlikely for the result of the meta-analysis not to be significant. Given these data and the current state of research in this field, it is reasonable to conclude that results support fairly robust conclusions.

Identifying mediators is a first step in understanding how psychotherapy works; the next step is testing these mediators in robust clinical trials. From this perspective, clinical trials might take advantage of their opportunities to investigate mediators of treatment by formulating a priori hypotheses aimed at investigating mechanisms of change for that particular study and by having sufficient intermediate or follow up assessments of hypothesized mediators and outcome indicators. Identifying factors that are responsible for amelioration or deterioration in the course of a specific disorder, during or after the treatment, along with factors responsible for dropping out, may be a crucial step in clarifying change curves for various disorders. It may also be the key to evidence-based intervention protocol elaboration and implementation, and, on the long run, the key to evidence-based training in psychotherapy.

Despite its limitations, our study provides the most comprehensive review to date of specific mediators in CBT and is, to our knowledge, the first study in this respect. It also provides further evidence for potential mechanisms of change in CBT. Mediators identified to this date are now suitable candidates for further research. Our results may stand for an excellent starting point for various areas of research and treatment development.

STUDY 2. INVESTIGATION OF MEDIATORS IN A RANDOMIZED CLINICAL TRIAL USING COGNITIVE AND BEHAVIORAL BIBLIOTHERAPY FOR SUBTHRESHOLD DEPRESSION [3]

Depression and subthreshold depression

Depression is one of the most prevalent mental disorders. For instance, it is estimated that that 9.1% of adults from the United States of America meet the criteria for current depression (Center for Disease Control and Prevention, 2010) and over the course of their lifetime more than 15% will experience an episode of depression (National Institute for Clinical Excellence, 2009). Depression is viewed as a spectrum of disorders

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[3] This study was accepted for publication.

Moldovan, R., Cobeanu, O., & David, D. (in press). Cognitive Bibliotherapy for Mild Depressive Symptomatology: Randomised Clinical Trial of Efficacy and Mechanisms of Change. *Clinical Psychology and Psychotherapy.*

including dysthymia, minor depression, major depression, and mixed depressive syndromes (Angst et al., 2003; Judd & Akiskal, 2003; Kendler & Gardner, 1998). These disorders significantly interfere with a person's daily functioning such as the ability to work, sleep, study, eat and enjoy once pleasurable activities (Horwath, Johnson, Klerman, & Weissman, 1992). Not surprisingly, the projections of the World Health Organization (1996) indicate that depression will be the highest-ranked cause of disease burden in developed countries by the year 2020.

In recent years there has been a greater recognition of the need to consider depression that is 'subthreshold' (NICE, 2009). Yet, there is no accepted classification for subthreshold depression in the current diagnostic systems, with the closest being minor depression, which is a research diagnosis in DSM-IV, or dysthymia. The descriptors used in recent international guidelines (NICE, 2009) generally cite the American Psychiatric Association (2000) and point to several instruments assessing levels of depression, such as the Beck Depression Inventory (BDI) cut-offs: 0-9 (not depressed), 10-16 (subthreshold), 17-29 (mild to moderate), 30+ (moderate to severe). In the present study, we used these descriptors for assessing subthreshold depression.

Recent research has started to describe the personal and social costs associated with subthreshold depression. It has a substantial impact on quality of life (Cuijpers, De Graaf, & Van Dorsselaer, 2004; Rapaport & Judd, 1998; Rowe & Rapaport, 2006), and it is associated with an increased risk of developing a major depression disorder (Cuijpers & Smit, 2004; Fergusson, Horwood, Ridder, & Beautrais, 2005) and relatively high mortality rate (Cuijpers & Smit, 2002; Cuijpers & Schoevers, 2004). Psychological treatments for subthreshold depression are being actively investigated and it is hoped that these treatments will help prevent the onset of major depression (Cuijpers, Smit, & Straten, 2007) by restructuring the mechanisms of change responsible for depression, as most studies are not conclusive regarding the theory of change of most interventions investigated.

Evidence-Based Treatments for Major and Subthreshold Depression

Evidence-based treatments for major depression are available and extensively used (NICE, 2009; Abbass, Sheldon, Gyra, & Kalpin, 2008; Cuijpers, van Straten, van Oppen, & Andersson, 2008; Cuijpers, van Straten, Warmerdam, & Andersson, 2008; David, Szentagotai, Lupu, & Cosman, 2008; Ekers, Richards, & Gilbody, 2008; Leichsenring, Rabung, & Leibing, 2004; Leichsenring & Rabung, 2008). In the case of subthreshold depression or mild to moderate depression, treatment is not as clear cut. Several "low-intensity" psychological interventions with potential benefit in the treatment of subthreshold depression have recently been suggested (NICE, 2009), such as guided self-help based on the principles of Cognitive-Behavioral Therapy (CBT). Self-help approaches may be particularly suitable for subsyndromal disorders (e.g., subthreshold depression) because they provide ready access to noninvasive and inexpensive treatment, and avoid the potential stigma of specialist referral (Cuijpers, 1997; Bower, Richards, & Lovell, 2001; Williams, 2001). Psychological treatments are therefore increasingly being provided in written format (i.e., bibliotherapy). Bibliotherapy refers to self-managed interventions that are based on validated and specific written materials and are generally facilitated by a healthcare professional. Most often, this facilitation is limited to introducing, monitoring and reviewing the outcome of treatment (NICE, 2009).

Bibliotherapy has been increasingly used in depression (Cuijpers, 1998; Starker, 1988a, 1988b; Ackerson, Scogin, McKendree-Smith, & Lyman, 1998; Floyd, Scogin, McKendree-Smith, Floyd, & Rokke, 2004; Floyd et al., 2006). Most forms of

bibliotherapy are based on principles from CBT (Gregory, Canning, Lee, & Wise, 2004), and they are designed to provide patients with means for restructuring key cognitive processes that contribute to depression. As recently reviewed (Anderson et al., 2005; Cuijpers, Smit & van Straten, 2007; Gellatly et al., 2007; Richardson, Richards, & Barkham, 2008), several bibliotherapy interventions in depression have been evaluated in randomized clinical trials: *Coping with Depression* (Lewinsohn, Antonucci, Brekenridge, & Teri, 1984); *Managing anxiety and depression* (Holdsworth & Paxton, 1999); *Feeling good – the new mood therapy* (Burns, 1999); *What should I do? A handy guide to managing depression and anxiety* (Kennedy & Lovell, 2002; Mead, MacDonald, Bower et al., 2005).

There is a growing literature indicating that psychological treatments for subthreshold depression are effective (Clarke et al., 2001; Lynch, Tamburrino, & Nagel, 1997; Mossey, Knott, Higgins, & Talerico, 1996; Willemse, Smit, Cuijpers, & Tiemens, 2004). A recent meta-analysis (Cuijpers et al., 2007), which included randomized controlled studies that investigated the effects of psychological treatments (i.e., mostly CBT), indicated a moderate effect size on short-term and small effect size at 1-year follow-up.

This randomized controlled study contributes to the literature by investigating the efficacy of CBT-based bibliotherapy in subthreshold depression, and identifying cognitive mechanisms of change for this intervention.

The current study

Our first objective was to investigate the overall treatment efficacy of CBT-based bibliotherapy in subthreshold depression. We hypothesized that bibliotherapy would significantly decrease depressive symptoms compared to delayed treatment, placebo and no-treatment. The very limited literature on predictors of psychotherapy effectiveness (e.g., Lambert, 1992; Lambert, 2003) suggests that there are a number of non-specific effects of psychological interventions that could account for improvement in psychotherapy, such as working alliance, patient characteristics, placebo or natural remission (Bertisch et al., 2009; Schoevers et al., 2003; Schoevers, Deeg, van Tilburg, & Beekman, 2005; Stek et al., 2006). These non-specific effects were controlled by including a placebo condition and a no-treatment condition. The latter condition shows the natural course of depressive symptoms. We specifically hypothesized that while bibliotherapy will result in decreases of both depressive symptoms and maladaptive cognitions, placebo will only be associated with a temporary decrease in symptoms. We expected no significant change in depressive symptoms or maladaptive cognitions in the delayed and no-treatment conditions.

We also wanted to investigate the effects of bibliotherapy on cognitive factors that may contribute to depression: negative automatic thoughts, dysfunctional attitudes and irrational beliefs. We hypothesized that bibliotherapy would decrease maladaptive cognitions and these cognitive changes would mediate the effects of bibliotherapy on depressive symptoms.

Method

Design

Participants were allocated equally between one of the four parallel arms corresponding to treatment conditions: (1) immediate-treatment (bibliotherapy); (2) delayed-treatment (wait list); (3) placebo; and (4) no-treatment. The main outcome was

represented by depressive symptoms. Automatic thoughts, dysfunctional attitudes and irrational beliefs were also assessed and hypothesized to have mediating effects.

Considering that previous studies (Cuijpers, 1997; Cuijpers et al., 2007; Gregory et al., 2004), which investigated the efficacy of bibliotherapy, suggested moderate to large effect sizes, we anticipated a similar effect size in our study. Power calculations (Cohen, 1988) for the study indicated that 18 to 42 subjects per group would allow us to detect a medium to large effect size with power above the traditional 0.80 level and alpha .05. Therefore, the recruitment of 96 patients in this study provided sufficient statistical power to address the major research questions, even after considering study attrition (an anticipated rate of 10% of the patients) (Jacobson et al., 1996).

Participants

Participants were all first year psychology students. Eligibility criteria were: (1) scoring between 10 and 16 on Beck Depression Inventory (BDI); and (2) not being in psychotherapy or on psychotropic medication. Students who were not eligible for this study (they had scores higher than 16) were referred to other ongoing studies investigating and treating depression. The initial sample consisted of 96 participants (84 females and 12 males) with a mean age of 23.03 (SD=2.17). Univariate ANOVAs showed no significant differences between treatment groups regarding any of the demographic variables (e.g., age, sex).

Treatment conditions
Bibliotherapy. Participants in the bibliotherapy condition received an adapted version of *Feeling Good* (Burns, 1980). The book has a theoretical foundation derived from Beck's (1970) cognitive theory of depression; its efficacy for mildly and moderately depressed adults has been investigated in previous clinical trials (Ackerson et al., 1998; Floyd et al., 2004; Jamison & Scogin, 1995; Scogin, Jamison, & Gochneaur, 1989). *Feeling Good* has a 6th-grade reading level and was previously rated as highly interesting (Scogin et al., 1989). Examples of sections in the book are: "Understanding Your Moods: You Feel the Way You Think," "Ways of Defeating Guilt," and "Ways to Overcome Procrastination". Bibliotherapy was designed as a one month treatment during which 5-minute weekly telephone calls were made to participants in order to discuss potential questions about the reading material or other practical concerns about the study.
Delayed treatment. Participants in the delayed bibliotherapy group were placed on a waiting list for one month.
Placebo. Participants in the placebo group received a book similar to the bibliotherapy material in terms of aspect and structure. The reading material included practical advice about how to be more organized at home or at the workplace. Five-minute weekly telephone calls were also made to this group of participants in order to discuss potential questions about the reading material or the study. When all assessments were completed, they were offered the bibliotherapy material. With this group we intended to investigate the role of non-specific effects of psychological interventions, specifically to observe whether and to what extent participants felt less depressed by receiving a psychological intervention with no "active" ingredients.
No-treatment. Patients in this group were told that they could not be included in the current study, but that they might be contacted for other studies. They were invited to complete all measures, at all assessment times. When all assessments were completed, they were offered the bibliotherapy material. Our objective with this group was to

investigate the likely course of depressive symptoms when no treatment was implemented, expected or simulated.

Measures

Outcome measure. All patients were evaluated at pretreatment, midtreatment, posttreatment, and 3-month follow-up. To assess depressive symptoms, patients were examined using BDI-II (Beck, Rush, Shaw, & Emery, 1979; Beck, Steer, & Brown, 1996). BDI-II is one of the most widely used measures of depression symptoms, and it includes 21 items referring to various psychological and physical symptoms (e.g., feeling sad, guilty, hopeless, being agitated).

Cognitive mechanisms. The Automatic Thoughts Questionnaire (ATQ; Hollon & Kendall, 1980), the Dysfunctional Attitude Scale (DAS; Weissman & Beck, 1978) and the General Attitudes and Beliefs Scale (GABS; Lindner, Kirkby, Wertheim, & Birch, 1999) were used to asses cognitive mechanisms relevant to depression, at pretreatment, midtreatment, posttreatment, and 3-month follow-up. ATQ is a 30-item self-report measure used to asses depression-related cognitions, with good convergent validity, internal consistency, and test-retest reliability (David, 2007; Harrell & Ryon, 1983). ATQ has also been shown to be sensitive to change in depression level (Eaves & Rush, 1984). DAS is a 40-item self-report instrument that measures attitudes that, according to the cognitive theory of depression, contribute to vulnerability for depression. Adequate internal consistency and test-retest reliability for DAS have been previously reported (David, 2007; Hammen and Krantz, 1985). GABS is a 26-item self report instrument that measures irrational cognitive processes (e.g., demandingness, awfulizing, global evaluation, low frustration tolerance) related to six content areas: achievement, approval, comfort, justice, self and others. Adequate psychometric properties have been reported in the literature (David, 2007; DiGiuseppe, Leaf, Exner, & Robin, 1988).

Comprehension. For the assessment of the comprehension and retention of the bibliotherapy material we used the Cognitive Bibliotherapy Test (adapted after *Feeling good* - Burns, 1980), a 20-item true/false scale, which has been shown to have good validity, being able to ascertain participants' comprehension and retention of the material, as well as discriminate between those who read the book and those who did not (Scogin, Jamison, Floyd, & Chaplin, 1998).

Procedure

Potential participants were assessed for eligibility through an initial assessment of depressive symptoms using BDI-II. A meeting was then organized with the participants who met inclusion criteria (e.g. a BDI-II score between 10 and 16) at which time a brief description of the study was provided by the principal investigator. Those who were interested in participating in the study were invited to sign an informed consent form and complete pretreatment measures.

A randomization plan was generated by an independent researcher in order to randomly allocate participants to one of the four conditions: immediate-treatment (bibliotherapy); delayed-treatment; (wait list); placebo; or no-treatment.

Participants filled in electronic versions of all of the above self-report measures. Participants in the bibliotherapy group were assessed at pretreatement (Time 1), at middtreatment (Time 2: 2 weeks after the beginning of the treatment), at posttreatment (Time 3: after one month of treatment), and 3-month follow-up (Time 4). Participants in the placebo, delayed-treatment and no-treatment groups were assessed at the same Times as participants in the bibliotherapy group.

Participants assigned to the bibliotherapy condition were given the bibliotherapy book along with explicit instructions on how to use the designated sections in the book (i.e., should they decide to do any of the exercises suggested in the book) and were given one month to complete the intervention. During this time, weekly telephone calls were made to participants. The telephone calls did not exceed 5 minutes and no counseling or advice was provided. During these phone calls, the researcher answered any questions participants had concerning the study or the reading material; participants were asked about the number of pages they read and the number of exercises they completed. Those who completed their book in less than one month were encouraged to review the material until a posttreatment assessment could be arranged.

Participants in the placebo condition were also telephoned weekly during their one-month intervention; during telephone calls, which did not exceed 5 minutes, the researcher answered any questions the participants had concerning the study or the reading material.

Participants in the delayed bibliotherapy group were placed on a waiting list for a month. After the waiting period, they received the bibliotherapy intervention.

Data Analysis and Statistics

Statistical analyses were conducted using the intent-to-treat principle: the analysis included all randomized patients in the treatment group to which they were assigned, regardless of their protocol adherence, and/or subsequent withdrawal from treatment or assessments. The last available score on each outcome measure served as termination score for drop-outs.

Posttreatment BDI-II scores served as the primary measure of the treatment outcome (i.e., depressive symptoms). Analyses of variance were performed to compare the efficacy of the treatment. Repeated measure ANOVA was used to investigate the course of depressive symptoms. Follow-up analyses were conducted to determine if treatment gains were maintained 3 months after the treatment. In order to investigate mechanisms of change, mediation analyses and repeated measures ANOVA were used to determine whether the intervention effects can be accounted for by the hypothesized mechanisms of change, the course of these mechanisms while in treatment, and whether gains are maintained at 3 months follow-up. Treatment status was "dummy" coded as an independent variable (see Treadwell & Kendall, 1996). An alpha level of .05 was used for all statistical tests.

Procedures suggested by Baron and Kenny (1986) were used to examine whether maladaptive cognitions mediated the effects of bibliotherapy on depressive symptoms. Analyses require that potential mediators (i.e., automatic thoughts, dysfunctional attitudes and irrational beliefs) are correlated with both the dependent (i.e., depressive symptoms) and the independent variables (treatment condition), then that three regression analyses be completed for each of the mediators investigated. First, the proposed mediator is regressed onto the independent variable. Second, the dependent variable is regressed onto the independent variable. Finally, the dependent variable is regressed onto both the proposed mediator and the independent variable. Mediation is suggested if the independent variable affects the mediator in the hypothesized direction in the first equation; if the independent variable affects the dependent variable in the appropriate direction in the second equation; if the supposed mediator affects the dependent variable in the third equation; and, if the effect of the independent variable in the third equation is zero or less than in the second.

Results

Attrition
The flow diagram bellow illustrates the progress through the phases of the trial (see Fig. 1).

Enrollment

Assessed for eligibility (n = 335)

Excluded (n = 239)
♦ Not meeting inclusion criteria (n = 231)
♦ Declined to participate (n = 8)

Randomized (n = 96)

Allocation

| Allocated to Bibliotherapy (n = 24) ♦ Received allocated intervention (n = 21) ♦ Did not receive allocated intervention (n = 3) Reason: Dropouts 3 | Allocated to Delayed Treatment (n = 24) ♦ Received allocated intervention (n = 22) ♦ Did not receive allocated intervention (n = 2) | Allocated to Placebo (n = 24) ♦ Received allocated intervention (n = 21) ♦ Did not receive allocated intervention (n = 3) Reason: Dropouts 3 | Allocated to Natural evolution (n = 24) ♦ Received allocated intervention (n = 20) ♦ Did not receive allocated intervention (n = 4) |

3 Months Follow-

| Lost to follow-up (n = 1) Reason: unknown | Lost to follow-up (n = 2) Reason: unknown | Lost to follow-up (n = 1) Reason: unknown | Lost to follow-up (n = 4) Reason: unknown |

Analysis

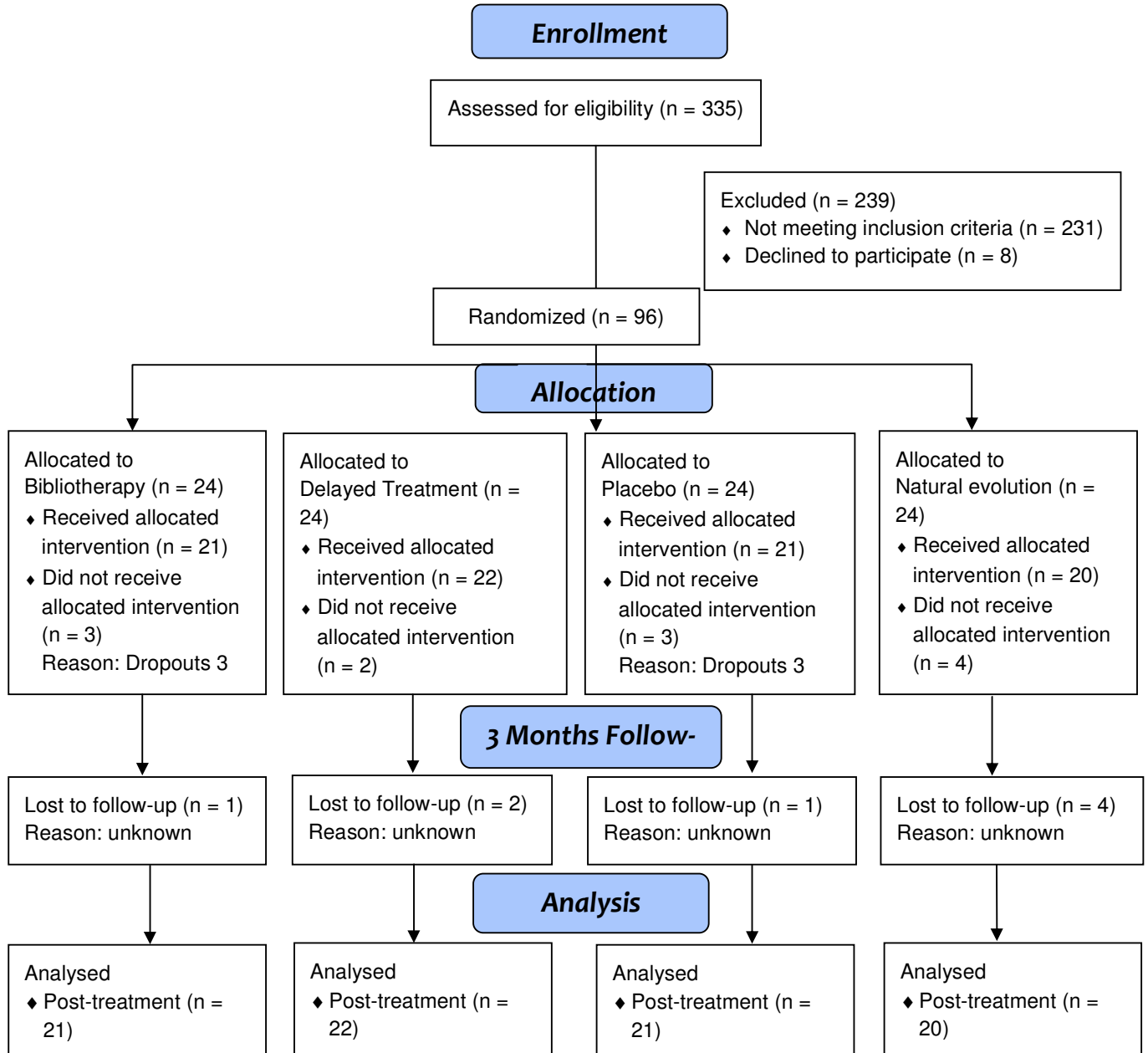| Analysed ♦ Post-treatment (n = 21) | Analysed ♦ Post-treatment (n = 22) | Analysed ♦ Post-treatment (n = 21) | Analysed ♦ Post-treatment (n = 20) |

Figure 1. Flow diagram of the progress through the phases of the trial

Three hundred and thirty five students responded to various announcements regarding the study and were invited to complete an online BDI-II assessment. One hundred four eligible students were invited via email to participate in the research. A total of N = 96 individuals entered the study.

Two persons discontinued before commencing treatment in the delayed-treatment condition, three during the placebo intervention and four from the no-treatment group whereas three dropped out during bibliotherapy. A total of 12 participants dropped out of the study before the posttreatment assessment. There were no significant differences between number of dropouts in the active treatment group and the other conditions.

Treatment outcome

Table 1 summarizes the outcomes of the randomized clinical trial, by condition and by assessment time. We compared all conditions on initial levels of depressive symptoms to establish if there were any significant differences between conditions before treatment. There were no significant differences between the BDI-II scores before the waiting period and the pretreatment assessment for the delayed-treatment group; also, no significant differences between groups at the pretreatment assessment of depressive symptoms (Time 1) were identified. Thus, participants in all four groups had comparable levels of depression prior to entering the trial.

Table 1. Means and Standard Deviations for depressive symptoms, at all times, by group

Time				
Variable	1	2	3	4
Bibliotherapy (N = 24)[a]				
BDI				
M	11.7	6.8	7.7	7.2
SD	2.2	5.0	4.8	4.9
Delayed treatment (N = 24)[b]				
BDI				
M	12.7	9.20	12.0	6.7
SD	2.3	9.0	7.9	5.2
Placebo (N = 24)[c]				
BDI				
M	11.7	9.9	7.1	10.2
SD	1.6	6.1	5.3	4.8
No treatement (N = 24)[d]				
BDI				
M	11.3	11.1	11.0	9.2
SD	1.9	8.1	6.1	5.4

a, b, c, d: Time 1 = pretreatement, Time 2 = middtreatment, Time 3 = posttreatment, Time 4 = follow-up

An initial ANOVA was conducted to evaluate overall treatment efficacy. The independent variable in this analysis was treatment group (bibliotherapy vs. placebo vs. delayed-treatment vs. no-treatment). The dependent variable was the BDI at

posttreatment. Analyses yielded significant differences between groups: $F[3,92] = 3.43$, p < .05. Post-hoc analyses (Tukey HSD) indicated that the bibliotherapy group significantly differed from the delayed-treatment group and the no-treatment group on the BDI, but did not differ significantly from the placebo group.

Repeated measure ANOVA (for the three assessment times) indicates a significant decrease in depressive symptoms ($F[2,21] = 8.21$, p < .05, $\eta^2 = 0.44$) for the bibliotherapy group. The delayed treatment group and the no-treatment group do not differ significantly from Time 1 to Time 2, and respectively, Time 3. Yet, there was a decrease in depressive symptoms for the placebo group ($F[2,21] = 8.21$, $\eta^2 = 0.42$).

The analyses for the bibliotherapy group were conducted to determine if treatment gains were maintained at 3-month follow-up. The results indicated that there were no significant differences between Time 3 and Time 4 assessments in terms of depressive symptoms, suggesting that treatment gains were maintained. We also conducted analyses to determine the course of depressive symptoms for the no-treatment group; inspection of the means indicated a decrease of BDI-II scores, particularly at 3-month follow-up, but differences are not significant. When investigating the evolution of the depressive symptoms for the placebo group at 3-month follow-up (compared to the assessment immediately following intervention), a significant increase was yielded: $t[23] = 2.45$, p < .05, Cohen's d = 1.16, which suggests gains were not maintained at follow-up.

Mechanisms of Change

After determining that the intervention was efficient in terms of the outcome, we investigated the influence of the intervention on the hypothesized mechanisms of change. The final question to be answered was whether the intervention effects could be accounted for by the hypothesized mechanisms of change.Means and standard deviations for each of the hypothesized mechanisms of change by condition and by assessment time are shown in Table 2.

Table 2. Means and Standard Deviations for hypothesized mechanisms of change, at all times, by group

Variable	Time			
	1	2	3	4
Bibliotherapy (N = 24)[a]				
ATQ				
M	31.5	22.4	24.4	23.6
SD	6.6	11.7	4.3	5.1
GABS				
M	60.0	57.0	49.2	48.2
SD	11.4	12.8	12.8	11.6
DAS				
M	117.6	112.5	99.4	101.8
SD	19.6	22.4	24.0	23.4
Delayed treatment (N = 24)[b]				
ATQ				
M	35.1	29.1	33.4	22.4
SD	8.8	16.9	11.8	4.9
GABS				

M	62.9	59.15	58.8	52.4
SD	11.1	11.75	11.5	12.2
DAS				
M	116.1	117.84	117.1	106.4
SD	23.5	28.8	24.7	19.8
Placebo (N = 24)[c]				
ATQ				
M	33.6	30.7	30.4	29.7
SD	7.6	13.5	9.6	6.8
GABS				
M	60.5	58.7	55.5	57.2
SD	8.9	10.7	10.5	9.7
DAS				
M	125.9	126.8	122.8	124.6
SD	27.6	21.8	27.0	24.5
No treatment (N = 24)[d]				
ATQ				
M	33.9	33.1	31.6	29.6
SD	13.4	14.4	14.5	9.6
GABS				
M	64.1	62.5	59.5	61.4
SD	12.0	12.6	13.5	12.2
DAS				
M	132.0	129.2	130.3	132.4
SD	23.1	26.8	29.7	22.8

a, b, c, d: Time 1 = pretreatement, Time 2 = middtreatment, Time 3 = posttreatment, Time 4 = follow-up

ANOVAs were conducted to evaluate the connection between participation in a treatment condition and changes in hypothesized mechanisms of change at posttreatment. The independent variable in this analysis was treatment group (bibliotherapy vs. placebo vs. delayed treatment vs. no-treatment). The dependent variables were ATQ, GABS and DAS. Results of the analysis of variance indicated that the groups differed significantly for all measures: on ATQ, $F[3,92] = 2.45$, $p < .05$; GABS, $F[3,92] = 3.57$, $p < .05$; and DAS, $F[3,92] = 4.30$, $p < .05$.

Post-hoc analyses indicated significant differences between the bibliotherapy and delayed-treatment means on ATQ: MD = 9.66, $p < .05$, Cohen's d = 0.93; GABS: MD = 12.2, $p < .05$, Cohen's d = 0.70; and DAS: MD = 20.33, $p < .05$, Cohen's d = 0.73. No differences were identified between the delayed-treatment and placebo or natural evolution group on any of the mechanisms measures.

Repeated measures ANOVA indicated a significant decrease from Time 1 to Time 2 and Time 3 in automatic negative thoughts ($F[2,21] = 7.20$, $p < .05$, $\eta^2 = 0.27$), general attitudes and beliefs ($F[2,21] = 24.28$, $p < .05$, $\eta^2 = 0.61$) as well as dysfunctional attitudes ($F[2,21] = 9.93$, $p < .05$, $\eta^2 = 0.58$] for the bibliotherapy group. In contrast, the placebo group, the delayed treatment group and the no-treatment group did not differ significantly in terms of any of the cognitions assessed throughout the intervention.

Analyses were conducted to determine if treatment gains at the cognitive level were maintained at 3-month follow-up. The results indicated that there were no

significant differences between Time 3 and Time 4 assessments for any of the cognitive mechanisms identified, suggesting that treatment gains were maintained.

Mediation analyses

Our data met requirements for mediation when using a treatment condition as independent variable, automatic thoughts as mediator and depressive symptoms as dependent variable (correlation coefficients are presented in Table 3).

Table 3. Correlation coefficients for all variables at Time 3

	BDI	ATQ	DAS	GABS	Treatment
BDI	-				
ATQ	0.68**	-			
DAS	0.39**	0.54**	-		
GABS	0.43**	0.55**	0.59 **	-	
Tratment	-0.38*	-0.51**	-0.40*	-0.48**	-

* Correlation is significant at .05 level
** Correlation is significant at .01 level

As predicted, depressive symptoms were significantly related to automatic thoughts ($r = 0.68$, $p < 0.01$) and treatment condition ($r = - 0.38$, $p < .05$). When regressing depressive symptoms on both treatment condition and automatic thoughts, the standardized coefficient for treatment was reduced from - 0.38 ($p < .05$) in the second equation to 0.03 ($p > .05$) in the third equation while the standardized coefficient for the automatic thoughts in the third equation was 0.84, $p < .05$. Sobel test confirmed the significant mediation: $z = 5.33$, $p < .05$; thus, the role of automatic thoughts in mediating the impact of cognitive bibliotherapy on depressive symptoms was supported by these findings. In the case of dysfunctional attitudes and irrational beliefs, the mediation models were not supported.

Conclusions and discussion

As hypothesized, we found that bibliotherapy resulted in both statistically and clinically significant changes in depressive symptoms and maladaptive cognitions, while placebo was only associated with a temporary decrease in symptoms without any changes at the cognitive level. Bibliotherapy was also found to be superior to the delayed-treatment and no-treatment conditions both in terms of symptoms and cognitions. In addition, we tested the meditation of cognitions and found evidence that automatic thoughts mediated the effect of bibliotherapy on depressive symptoms. Therefore, these results support the view that cognitive bibliotherapy is effective for subthreshold depression and cognitions are the likely mechanism of change.

The present findings are in line with previous studies indicating a moderate effect of other psychological treatments (e.g., CBT) on subthershold depression. Our study focused on CBT-based bibliotherapy and found it to be an efficient treatment for subthreshold depression (Cuijpers, 1997; Cuijpers et al., 2007; Gregory et al., 2004; Jamison & Scogin, 1995; Scogin, Hamblin, & Beutler, 1987; Scogin et al., 1989). The present results support Beck's (1970) cognitive theory of depression and extend previous research (Ackerson et al., 1998; Treadwell & Kendall, 1996) that found cognitive mechanisms such as automatic thoughts as mediating change in depressive symptoms.

Together these results indicated that following treatment, bibliotherapy was superior to placebo (in terms of cognitions) and to delayed treatment and no treatment (in terms of both symptoms and cognitions). Reading a book that does not have "active ingredients" (e.g., the one used in the placebo group) may contribute to the reduction of depressive symptoms on short-term. However, these reductions will not be maintained on the long-term because the cognitive mechanisms (e.g., automatic thoughts) responsible for depression are not restructured. Follow-up assessment results clearly indicated that while bibliotherapy effects were generally long-lasting (i.e., the significant improvements achieved during treatment were maintained both in terms of symptoms and mechanisms), the placebo group lost the gains temporarily achieved by reading the placebo book and returned to the level of depression symptoms from baseline.

The present study is not without its limitations. In light of the small sample size, all findings should be interpreted with caution. Using power calculations (Cohen, 1988) and guidelines for interpreting effect sizes (Cohen, 1977), a sample of 24 participants per group provides enough power to detect medium to large effects, but not small effects; therefore, our conclusions regarding differences between conditions are only suggestive from this perspective and are in need of additional empirical evidence. This study also has limitations common to other treatment studies: due to convenience, we recruited first year psychology students; their knowledge about psychology, psychotherapy and depression were assumed to be negligible, but it is very likely that psychology students willing to volunteer for a research study are different to some extent from mildly depressed adults from the community. Consequently, the results of this study may not apply to all depressed adults.

In spite of these limitations, we did find clear indications that cognitive bibliotherapy was effective in the treatment of subthreshold depression. In addition to previous results, we brought an important contribution to the bibliotherapy literature by describing the effects on cognitive factors involved in depression: most participants undergoing treatment were able to reduce their depressive symptoms as well as change their dysfunctional attitudes, irrational beliefs and automatic thoughts (which were also found to mediate treatment's effect); these gains were maintained three months following treatment.

In conclusion, this study showed that cognitive bibliotherapy was effective in the treatment of subthreshold depression and that changes in automatic thoughts mediated its effects on depressive symptoms.

STUDY 3. INVESTIGATION OF PREDICTORS OF OUTCOME IN A RANDOMIZED CLINICAL TRIAL USING ONE SESSION TREATMENT OF VIRTUAL REALITY, AND COGNITIVE BEHAVIORAL THERAPY FOR SPECIFIC PHOBIA. THE CASE OF WORKING ALLIANCE, EXPECTATIONS AND THERAPISTS' PERFORMANCE

Introductory remarks

Phobias are described as an exaggerated, irrational fear of specific objects or situations, characterized by significant avoidance of any *in vivo* or *in vitro* exposure to fear stimuli or enduring it with great distress when avoidance is not possible. About 4.4% percent of the adult population in the USA suffers from one or more phobias (Narrow et al., 2002) which will mostly persist for years and go chronic; complete remissions without treatment are very rare.

Social phobia is regarded as the most common anxiety disorder and the 3rd most common psychiatric disorder (Craske, 1999), having a one year prevalence of 3.2% in the US. It is characterized by excessive and persistent anxiety in social situations ranging from public speaking to performing a task in the presence of others. Just like simple phobia, it has an early onset (childhood or adolescence) and it usually becomes chronic without treatment. Most often, the severity of symptoms and degree of impairment vary, given one's work demands and the stability of social relations. Recent studies show that in 93% of the cases, social phobia interferes with work performance, social life (in 82% of the individuals) and close relationships (in 71% of the individuals) (Ruscio et al., 2008; Wallach, 2009).

A specific phobia is an intense, irrational fear of something that poses little or no actual danger. Adults with phobias most often realize that these fears are irrational but they often find that facing, or even thinking about facing, the feared object or situation brings on severe anxiety. Specific phobias are rather common as they affect 19.2 million adults in the US. They are also known to be twice as common in women than in men (Kessler et al., 2005). Among the simple phobia subtypes established by DSM – IV (some of the most common involve closed-in places, heights, escalators, tunnels, water, and injuries involving blood etc.), fear of flying has become very common in modern societies. Statistics in US and Europe show that 10%-15% percent from the general population suffer from fear of flying and about 20%-25% experience high levels of anxiety during flying (Ost, 1997; Muhlberger, 2002). Acrophobia or fear of heights it also rather common and it is known to affect 1 in 20 adults (Coelho, 2009).

Psychological treatments of Phobias

To a great extent, phobia is the result of learning, thus the disorder was developed by either the means of classical conditioning or vicarious learning. With classical conditioning, fear is maintained by the avoidance behavior. Given that avoidance prevents the experiencing of phobic symptoms (subjective anxiety and physiological arousal); the exaggerated fear (phobia) is not solved but negatively reinforced (therefore, exposure has the role of fear extinction). In addition to conditioning studies, there is a large amount of research showing that both dysfunctional cognitions (Beck, 1976) and irrational beliefs (Ellis, 1979) explain to a great extent anxiety symptoms. To date, there is extensive empirical data supporting the efficacy of CBT in treating phobias (Ost et al., 1997; Chambless et al., 1998; Choy et al., 2007; Zlomke et al. 2008; Wolitzky-Taylor et al., 2008; Wallach et al. 2009).

As far as exposure is concerned, several studies provide empirical evidence showing that exposure (both in vivo and in virtual reality) can significantly influence treatment outcome (Rothbaum et al, 2000; Emmelkamp et al., 2002; Kamphuis & Telch, 2000; Powers et al., 2004; Rowe & Craske, 1997a,b; Sloan & Telch, 2002; Telch et al., 2004; Wolitzky–Taylor et al., 2008). For this study, VR was approached as a desensitization technique because of its advantages when compared to *in vivo* techniques: the capability to design a personalized exposure experience, low financial (i.e. taking a domestic flight) and time costs.

One session treatment

One session treatment was first introduced in a controlled study conducted by Ost et al. (1992) on injection phobia, followed by more controlled trials for flight anxiety (Ost et al., 1997) and claustrophobia (Ost et al., 2001). Results of these latter studies indicate that the improvements brought by 5 sessions of treatment (combining CBT with *in vivo*

exposure) over one session treatment are not significantly higher (Wolitzky–Taylor et al., 2008; Powers & Emmelkamp, 2008)

The current study

      The current study was structured around several objectives. First, we wanted to investigate the efficacy of one session treatment VRCBT in treating social and specific phobia; here, we were interested not only in whether treatment works (both in terms of outcomes and mechanisms), but also in knowing what is the course of change during treatment. Then, we concentrated on investigating if and to what extend do working alliance, patients' expectations and therapists' performance contribute to this change. From this perspective this research is innovative in that, currently there are no studies addressing simultaneously psychotherapy components such as working alliance, patients' expectations and therapists' performance: one session VRCBT treatment (e.g. for social and specific phobia) provided an excellent methodological framework to investigate these aspects.

Method

Design

      Participants who met the criteria for inclusion in the study were allocated equally between one of the two parallel arms corresponding to treatment conditions: (1) VRCBT treatment or (2) Wait list. Following the pre-test, the participants in the experimental condition entered the VRCBT one session treatment. The WL control group received no treatment until all participants in the experimental group completed the treatment.

Participants

      The inclusion criteria for the study were for the patients to be aged over 18 and to meet the DSM-IV diagnostic criteria for social phobia, or for one of the two specific phobias investigated (flight phobia and acrophobia). 32 subjects who met the criteria (15 females, 17 males) entered the study; 15 were diagnosed with social phobia (6 males and 9 females), 8 had acrophobia (6 males and 2 females) and 9 flight phobia (5 males and 4 females). The mean age of participants was 13.13 (SD = 12.05) years. Univariate ANOVAs showed no significant differences between groups regarding demographic variables (e.g. age, sex).

      A second category of participants was represented by the 4 clinical psychologists trained in cognitive and behavioral therapies who conducted all therapy sessions; none of them had previous experience in psychotherapy. A 5th therapist was trained in using the VR technology and was a co therapist during the VR exposure.

Assessment

      Measures used addressed both general and specific anxiety symptoms as well as measures specifically related to cognitive mechanisms hypothesized as responsible for anxiety symptoms. Additionally, specific VR related measures aimed at assessing immersion and presence were also used.

Outcome measures: The Structured Clinical Interview for DSM IV (SCID; First, Spitzer, Gibbon, & Williams, 1995) was used to establish if the participants met the diagnostic criteria for either social phobia or simple phobias - flight phobia or acrophobia. *Liebowitz Social Anxiety Scale* (LSAS, Liebowitz, 1987) includes 24 items, 13 relating to performance anxiety and 11 concerning social situations. *Flight Anxiety Situation*

Questionnaire (FAS; Nousi et al., 2008). This is a 32 item self-report measure, with participants assessing anxiety related to various flight situation. *State-Trait Anxiety Inventory –Y Form* (STAI-Y, Spielberger, 1973, 1983). It is a 40 items inventory; measuring anxiety as a state (S-Anxiety) and anxiety as a trait. *Subjective Units of Distress (SUDs).* In order to accurately describe high or low anxiety, participants were trained as to use a 0 to 100 scale (the Subjective Units of Distress, SUDs, Wolpe, 1973) in order to indicate the level of anxiety they experience. SUDs were used every 3 minutes during VR exposure.

Cognitive mechanisms.The Self Statements during Public Speaking Scale (SSPS, Hofmann & DiBartolo, 2000). This is a 10-item questionnaire consisting of two 5-item subscales: "Positive Self-Statements" and "Negative Self-Statements". *Fear of Negative Evaluation Scale – brief version* (BFNE; Leary, 1983). The brief version of the fear of negative evaluation scale (FNE; Watson & Friend, 1969, Collins et al., 2005) was chosen for this study given its benefits of quick administration and good psychometric properties. *Flight Anxiety Modality Questionnaire* (FAM; Gerwen et al., 1999). It is an 18-item self-report questionnaire, measuring 2 symptom modalities of anxiety expression in flight situations: (a) somatic modality - physical symptoms and (b) cognitive modality - distressing cognitions. *Expectations* were assessed by asking patients to rate on a Visual Analogue Scale (VAS) their answers. 3 expectations were assessed: (1) "To what extent do you expect your fear to get better?"; (2) "To what extent do you expect psychotherapy to help reduce your fear?"; (3) "To what extent do you expect Virtual Reality to help reduce your fear?"

Virtual reality measures. Immersive tendencies questionnaire (ITQ; Witmer & Singer, 1998). This 34 item scale measures the psychological state of feeling absorbed, or immersed in virtual reality. *Presence questionnaire* (PQ; Witmer & Singer, 1998). This scale evaluates the subjective experience of having been in the virtual environment, even when one is physically situated in another.

Psychotherapy measures. Working Alliance Inventory (WAI, Horvath & Greenberg, 1986, 1989). To assess the therapeutic alliance, we used the short version of the Working Alliance Inventory. The WAI is a 12-item self-report global measure of the working alliance.

Procedure

The one session treatment was preceded and followed by an assessment session where diagnosis was established and self-report measures were completed. The CBT protocol used for this study was based on REBT theory (Ellis, 1979) with participants learning to identify the irrational beliefs that lead to anxiety and unproductive behaviors (avoidance, escape etc.) and to dispute these irrational beliefs as well as assimilate alternative rational beliefs. Participants also learnt how the avoidance behaviors maintain anxiety instead of solving it and how exposure to the feared situation can reduce anxiety and avoidance tendencies. No type of exposure exercise was made during the CBT session, as this is covered by the VR exposure session. The CBT session ended with the therapist establishing together with the participants the hierarchy of their feared situations on a 7 point Likert scale (1 = no fear, 7 = extreme fear). This list served as input for orienting the flow of the VR exposure scenarios in order to make it as personally tailored as possible.

Given the one session treatment format examined in this study, the VR exposure consisted of 4 scenarios of 15 minutes each, separated by short breaks. The level of fear during exposure was measured using the Subjective Units of Discomfort (SUDs, Wolpe,

1973) ranging from 0 (no fear response) to 100 (overwhelming fear). Participants were trained to assess their fear on the 0-100 scale prior to the VR exposure and ratings were requested every 3 minutes. The mean of fear ratings was computed for each scenario.

4 therapists with similar backgrounds and training, with no previous experience in psychotherapy conducted all psychotherapy sessions. Their performance was assessed by listening to all recordings of the sessions and by rating their performance using the REBT Therapy Rating Scale.

Results

Treatment outcome

We first assessed and then compared all variables to determine if there were any significant differences between the two groups before treatment. Analyses revealed no significant differences between groups at the pre intervention assessment on any of the measures.

Following treatment, we evaluated overall treatment efficacy: the independent variable in this analysis was treatment group (immediate treatment and delayed treatment) and the dependent variables were measures assessing the treatment outcome and cognitive mechanisms. The analysis yielded no significant differences on any of the measures between the immediate treatment group and the delayed treatment group.

Further on, Paired Samples T Tests were performed in order to examine whether VRCBT treatment significantly reduced symptoms and cognitive mechanisms for pre- to post- treatement.

While no significant differences were identified for general measures (such as anxiety, irrational beliefs), except for acrophobia, all other results indicated significant differences between measures prior and post treatment.

Another result worth mentioning is the score for irrational beliefs: $t(30) = 1.80$, $p = .08$. Given the small number of participants in the study, it was important to estimate weather this tendency would reach statistical significance if the study sample was larger. Therefore we looked at the table of critical values for t-test and concluded that this result would have been significant at $p < .05$ if the sample of participant were $N = 35$.

In order to test the 3rd hypothesis, namely, a possible moderating effect of immersion and presence on the relation between pre-test and post-test anxiety was investigated. Results haven't reached statistically significance.

Course of change

In order to investigate the course of change during the single session treatment, we computed a mean of all SUDs per each scenario. Paired Samples T-Test was used to see if and when significant differences of the level of fear appear during this session. We did find significant differences between the first and the last subjective assessment of fear: $t(30) = 3.22$, $p < .05$.

Expectations

In order to investigate whether expectations have any impact on change, bivariate correlations were performed between the three expectations we assessed and change (the difference between pre intervention and post intervention scores). Data indicate significant correlations between expectations and all outcome changes, except for STAI-S. Expecting psychotherapy to help reduce fear explains 21% of gains in rational beliefs, 38% of improvement by reducing irrational beliefs and 22% of reduction of fear during

the intervention. Expecting VR to help reduce fear explains 13% of gains in rational beliefs, 23% of the decrease in irrational beliefs. Generally, expecting fear to get better explains 35% of the decrease in irrational beliefs and 16% of the decrease of fear during exposure.

Working alliance

The relation between working alliance (both assessed by therapist – WAI-T and by patients – WAI-C) and change (the difference between pre intervention and post intervention scores) was assessed by computing bivariate correlations. Results indicate significant correlations between working alliance, as measured by the patient, and change in anxiety (measured by means of subjective units of distress but not measured with STAI-S), rationality and irrationality. No significant correlations were found between working alliance, as rated by the therapist, and any of the outcome measures. Further analyzing this set of data, we can conclude the working alliance (assessed by the patient) explains 31% of the variance in rationality increase, 35% of the variance in irrationality reduction and 39% of anxiety during exposure.

Therapists' performance

Overall, therapy performance ranged from 46 to 62 with a mean of 55.37 (SD = 4.48). Further on, therapists' performance was correlated with therapy outcome. Therapists' performance did not correlate with change in rationality/irrationality or with general measures of anxiety. Also, most likely due to the very small number of patients with either social (N = 15), plane (N = 9) or heights (N = 8) phobia no significant association between results on any of these measures and therapists' performance were identified. However, change in subjective ratings of fear during exposure (mean SUD 1 - mean SUD 4) - did correlate significantly with therapists' performance: $r = .42$, $p < .05$. In other words, 19% of the change in anxiety occurring during psychotherapy is accounted for by therapists' performance. We also wanted to investigate whether therapists' performance is associated with working alliance (both assessed by therapists and assessed by patients). Results indicated that working alliance, assessed by patients is significantly correlated with therapists' performance ($r = .41$, $p = .05$). No such a relation was found between therapists' ratings of working alliance and their performance.

Conclusions and discussion

The hypothesis that immediate treatment is going to be superior to the delayed treatment group was not confirmed. Scores for all variables investigated were in the hypothesized direction but the level of significance was not reached. Given the small sample size these results are not unexpected. Second, differences between pre intervention and post intervention are significant in most cases which indicate that further studies, conducted within a larger sample size may identify significant effects. Third, working alliance (if measured by patients) seems to be a robust predictor of change both in terms of mechanisms and in terms of symptoms. Fourth, therapists' performance seems to be a solid predictor of change, explaining 19% of the change in anxiety occurring during psychotherapy is accounted for by therapists' performance. Fifth, patients' expectations seem to play a major role in explaining the outcome. This is in line with previous research investigating patients' expectations and placebo in explaining outcome.

To date, this is the first study conducted clinical sample that investigates the effects of one session treatment (VRCBT treatment) for social phobia and specific

phobias (flight phobia and acrophobia). Given the small sample of participants in the study, all results obtained should be interpreted with caution.

[4]STUDY 4. INVESTIGATION OF THERAPIST VARIABLES AND THEIR PERFORMANCE. THE CASE OF EXPECTATIONS, SELF EFFICACY, AND THERAPISTS' PERFORMANCE

Introductory remarks

Psychotherapist competence is an important factor related to process and outcome variables in psychotherapy (Barber & Crits-Christoph, 1996; Barber, Foltz, Crits-Christoph, & Chittams, 2004; Barber et al., 2006; Beutler et al., 2004) and the interest in this research area has greatly increased during the last two decades. In a broad sense, psychotherapist competence has been most often defined as someone's skillfulness in administering a treatment (Barber & Crits-Christoph, 1996; Barber et al., 2004). Recently, increasing attention has been given to identifying core competencies as a basis for defining and measuring trainee outcomes (Fouad et al., 2009). Additionally, attention has been paid to various areas of competence (e.g., therapeutic competence) that may involve components carried out with a certain degree of performance (e.g., implementation of a relaxation exercise).

Self-efficacy

Self-efficacy refers to an individual's perceived capability to perform necessary tasks to achieve goals; it is primarily a cognitive appraisal of one's capabilities to attain a prospective performance (Bandura, 1997). Self-efficacy is generally defined as one's concept of his or her ability to perform a particular task, in a specific context or domain. According to the social cognitive theory, people perform better on tasks for which they have higher self-efficacy.

Expectations

Another aspect that has enjoyed a long history in the psychotherapy literature is the expectancy factor (e.g., Weinberger & Eig, 1999). Expectations are generally approached as specific beliefs that we hold about the future state of affairs (Reinhard, 2009). Patient expectations have been regarded as a variable affecting the course of psychotherapy for more than 50 years. Yet, even though expectations are often considered a factor common to most psychotherapy systems, their importance is often undervalued. Moreover, psychotherapists' expectations are perhaps even more under-researched. More recently, however, researchers have begun to pay attention to the importance of expectations as a "pantheoretical" change ingredient.

The current study

The aim of the present study was to investigate the extent to which psychotherapists' expectations and self-efficacy influence their performance. Furthermore, our aim was to examine the effects of psychotherapists' performance in a specific intervention (i.e., a relaxation exercise) on the intervention efficiency. Based on theory and previous research, the following hypotheses were formulated: (1) psychotherapists' self-efficacy is positively correlated with their performance; (2)

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[4] This study has been submitted for publication in *Learning and Individual Differences*

psychotherapists' performance expectations are positively correlated with their performance; (3) the efficiency of the intervention is positively correlated with the psychotherapists' performance.

Method

Design

This study was designed as a quasi-experiment. The variables investigated were: psychotherapists' self-reported expectations and self-efficacy, psychotherapists' performance (rated by their supervisors) and the therapeutic task efficiency (rated by volunteers).

Participants

Forty four psychotherapists in training (henceforth "trainees") participated in this study. Participants (39 females and 5 males) had a mean age of 24 years (ranging from 23 to 28 years). Forty four community members (henceforth "volunteers") agreed to participate in this study. The sample consisted of 41 females and 3 males with a mean age of 28 years (ranging from 23 to 32).

Measures

Trainees self-report measures: The General Self-Efficacy Scale (SES: Jerusalem & Schwarzer, 1981) is a 10-item self-report measure designed to assess beliefs that one's actions are responsible for successful outcomes. *Visual Analogue Scales* (VAS) are a type of measurement instrument that assesses characteristics believed to range across a continuum of values and which cannot be easily directly measured. We used 3 VAS assessing trainees' expectations (1) to perform the intervention correctly; (2) for the intervention to be effective; and (3) for the volunteer to expect to become relaxed following the intervention. Trainees were asked to mark their answers on 13 cm long visual analogue scales ranging from "not at all" to "very much".

Supervisor-rated measures: Competence assessment protocols includes 10 items describing the most relevant aspects of the relaxation exercise. Trainees' competence was assessed by evaluating the degree to which they correctly performed each component.

Volunteer rated measures: Exercise efficiency was assessed by asking volunteers to rate, from 0 to 10, the degree to which they felt relaxed following the intervention.

Procedure

The relaxation session was approximately 15 minutes long and included (1) addressing common misconceptions about relaxation; (2) imagery for mental and physical relaxation; (3) suggestions for pleasant visual imagery; (4) suggestions to experience relaxation and peace; (5) a deepening procedure, and (6) instructions on how patients could use relaxation on their own.After participating to the relaxation exercise, volunteers were asked to rate, on a scale from 0 to 10, the degree to which they felt relaxed. Each intervention was video-recorded and then rated by two clinical psychologists and supervisors in CBT, who were instructed to assess trainees' administration of the relaxation exercise, as per the competence assessment protocol.

Results

Means and standard deviations for trainees' self-reported expectations and self-efficacy are presented in Table 1. Descriptive statistics are also presented for supervisors' assessments of trainees' performance and volunteers' ratings of the technique efficiency.

Table 1. Trainees' expectations, self-efficacy, performance and exercise efficiency

Variables	Mean (M) and Standard Deviations (SD)
Self-efficacy	M = 33.77 (SD = 3.12)
Expectation 1	M = 11.35 (SD = 1.69)
Expectation 2	M = 10.85 (SD = 1.65)
Expectation 3	M = 9.43 (SD = 2.00)
Performance	M = 43.39 (SD = 4.46)
Exercise efficiency	M = 7.93 (SD = .81)

Bivariate correlations were performed in order to test whether trainees' self-reports (i.e. expectations and self-efficacy) are associated with their performance (as assessed by their supervisors) and the efficacy of the relaxation technique they implemented (as reported by the volunteers). Results are shown in Table 2. None of the Pearson coefficients were significant ($p > .05$). The first two hypotheses were therefore not confirmed.

Table 2. Correlations between expectations, self-efficacy and performance

Trainees' variables	Trainees' performance
Self-efficacy	.03
Expectancy 1	-.18
Expectancy 2	-.04
Expectancy 3	.04

all $p > .05$

We then investigated the relationship between performance (as assessed by the supervisors) and intervention efficacy (as reported by the volunteers); the two variables were positively correlated ($r = .71, p < .05$). These results confirmed our third hypothesis.

Results indicate that trainee performance significantly explains the variance of the relaxation reported by volunteers. More specifically, 51% of the technique efficiency (i.e. degree of relaxation experienced by the volunteers) is accounted for by trainee performance. $r = .51$ indicates a medium effect size (Cohen, 1988).

Conclusions and discussion

Contrary to our hypotheses, we found that trainees' self-reported expectations and self-efficacy are not positively correlated with their performance, as assessed by their supervisors. Yet we found, as hypothesized, that trainees' performance (assessed by supervisors) is significantly associated with the intervention efficiency (rated by volunteers).

Taken together, these results indicated that apparently, at least in the early stages of their training in psychotherapy, trainee self-report measures do not seem to be a reliable predictor of their own performance or the efficiency of their intervention. Results are particularly interesting as the investigation of the impact of psychotherapist expectations and self-efficacy related to the intervention efficiency are no easy tasks. Our study offers an example of how to address psychotherapist related predictors and correlates of a specific psychological intervention.

The present study is not without limitations. In light of the small sample size, all findings should be interpreted with caution. Another limitation is the lack of pretest assessments of the degree to which the volunteers felt relaxed prior to the relaxation exercise. Future studies might try to replicate the present results on larger samples and develop this study by investigating more extensively psychotherapist-related predictors of their performance and their intervention outcome (e.g. experience, allegiance, personal characteristics etc.).

In conclusion, this study showed that psychotherapy trainees' self-reported expectations and self-efficacy, at least in the early stages of their training, seem to be an unreliable predictor of their performance (assessed by supervisors). Nevertheless, the intervention outcome (rated by volunteers) is highly dependent on their performance (assessed by supervisors).

[5]STUDY 5. INVESTIGATION OF THERAPIST VARIABLES AND OUTCOME IN A SHAME ATTACK EXERCISE. THE CASE OF EXPERIENCE, ALLEGIANCE, SELF EFFICACY AND UNCONDITIONAL SELF ACCEPTANCE

Introductory remarks

The literature indicates no reliable data in terms of therapists' attributes that best predict outcome; therapist gender, age or theoretical orientation have been generally been found to have a remarkably limited capacity to predict outcome (Beck, 1988; Beutler, Machado, & Neufeldt, 1994; Beutler, Malik, Alimohamed, Harwood, Talebi, Noble, & Wong, 2004; Lambert, 1989). Several previous studies (Blatt, Sanislow, Zuroff, & Pilkonis, 1996) concluded that therapists' demographics do not appear to impact on the outcome. Alternatively, therapists' skills and experience are usually considered more robust predictors of outcome (Beutler et al., 1994). The paucity of research in this area is even more marked as far as the supervisor-trainee relation is concerned. Nevertheless, several variables have been previously addressed independently, in various contexts (Beutler et al., 1994; Crits-Cristoph, Barnackie, Kurclas, Beck, Carroll, Perry, et al., 1991; Stein & Lambert, 1995): supervisors' experience, allegiance, unconditional self-acceptance and self-efficacy. As there are no previous studies investigating these specific constructs and the relations between them simultaneously, gathering empirical data and bringing some light into this matter was one of our main goals in this study.

Methodological strategy

Shame attack exercises are frequently used by Ellis and his colleagues (Grieger & Boyd, 1980; Wessler & Wessler, 1980) as they are thought to be methods for reducing

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[5] This study has been submitted for publication in *Professional Psychology: Research and Practice*

excessive sensitivity to the reactions of others. These techniques involve having someone intentionally perform activities that are likely to attract unfavorable attention and to test one's catastrophic thinking about the importance of what others will think. There is a general agreement (David, 2006) that, in the particular case of shame attack exercises, a good working alliance is needed in order to ask someone to do such an exercise as a homework assignment or a personal development technique. The definition of the working alliance that has garnered most consensus, and therefore was adopted here, is that of a collaborative relationship between therapist and client that can facilitate positive change for the client; it generally refers to the collaborative nature of the client-therapist interaction, their agreement on goals, and the personal bond that emerges in treatment (Bordin, 1976; Horvath, 1994

The current study

The main objective of the research was to identify some of the characteristics of the supervisors that best explain trainees' outcome. To be more specific, we formulated the following hypotheses: (1) Trainees supervised by more experienced therapists will have better outcomes than trainees supervised by less experienced therapists; (2) Trainees supervised by therapists with higher allegiance will have better outcomes than trainees supervised by less allegiant therapists; (3) Trainees supervised by therapists with higher self-efficacy will have better outcomes than trainees supervised by therapists with lower self-efficacy; (4) Trainees supervised by therapists with higher unconditional self-acceptance will have better outcomes than trainees supervised by therapists with a lower level of self-acceptance.

Method

Participants

Two types of participants were included in this study: therapists with various degrees of experience (supervisors) and therapists in training (trainees). Both supervisors and trainees were trained or being trained in Cognitive-Behavioral Therapy (CBT). Four supervisors participated in this study, with experience in supervising trainees in CBT between 1 to 10 years. A total of 33 trainees entered the study. The sample consisted of 29 females and 4 males. Participants had a mean age of 25 years (ranging from 21 to 34). Participation was voluntary.

Measures

The Unconditional Self-Acceptance Questionnaire (USAQ, Chamberlain & Haaga, 2001) is a 20-item self-report measure that was used to assess unconditional self-acceptance. *The General Self-Efficacy Scale* (SES, Schwarzer & Jerusalem, 1995) is a 10-item self-report measure designed to assess beliefs that one's actions are responsible for successful outcomes. *Working Alliance Inventory* (WAI, Horvath & Greenberg, 1989) is a 12-item self-report measure widely used in assessing the therapeutic alliance. *Visual Analogue Scales* assessing allegiance (1) in CBT being effective in developing unconditional self-acceptance and (2) in shame attacks being effective in developing unconditional self-acceptance were used. Supervisors were asked to mark their answers on 13 cm long visual analogue scales ranging from "not at all" to "very much". We also measured *participation* by trainees' binary self-report of whether they did the shame attack exercise or not.

Procedure

Sixty trainees were invited to take part in a three-hour group session of personal development; each was randomly allocated in one of four groups, each group corresponding to one supervisor. 33 trainees agreed to participate and signed an informed consent. The 4 supervisors were initially trained as to the session's aims, structure and content. During the session, supervisors focused on unconditional self-acceptance, its role and methods to develop it. At the end of the session, each supervisor recommended the same homework assignment: trainees were invited to do a shame attack exercise during the following week and send a brief report with the description of the exercise.

Results

Of the 60 trainees invited, a total of 33 agreed to participate in the current study. Their results - means and standard deviations for the unconditional self-acceptance and working alliance measures as well as the percentage of trainees that completed the shame attack exercise - are presented in Table 1.

Table 1. Trainees' results

Trainees' characteristics	Means (M) and Standard Deviations (SD)	Shame attack execution (%)
Unconditional self-acceptance	M = 95.43, SD = 15.77	
Working alliance	M = 72.75, SD = 7.35	
Shame attack		57.6%

Correlations were calculated in order to investigate whether trainees' ratings of the working alliance with their supervisor were associated with their unconditional self-acceptance ($r = .38$, $p < .05$) and the extent to which they executed the shame attack exercise ($\chi^2(18) = 11.33^*$, $p < .05$). Results are presented in Table 2.

Table 2. Correlations between trainees' scores and working alliance

Trainees' characteristics	Working alliance
Unconditional self-acceptance	. 38*
Shame attack	11.33* (df = 18)

$p < .05$

We also wanted to see if, as hypothesized, supervisors' characteristics significantly discriminated among trainees' outcomes. One way ANOVA indicated that more experienced supervisors had significantly better outcomes both in terms of trainees' adherence to the shame attack exercise and their level of unconditional self-acceptance: $F(2, 29) = 3.23$, $p < .05$ ($d = .94$).

Results also indicated that trainees' level of unconditional self-acceptance was significantly higher if their supervisor had a high level of unconditional self-acceptance: $F(1,30) = 6.86$, $p < .05$ ($d = 1.35$). Also, they did significantly more shame attack exercises than those whose supervisor had a lower level of unconditional self-acceptance.

Furthermore, results indicated significant differences in trainees' unconditional self-acceptance and adherence to the shame attack exercise when comparing their outcome in terms of their supervisors' allegiance in both CBT and shame attack exercises: $F(1,30) = 6.86$, $p < .05$ ($d = .95$) and $F(2,29) = 3.32$, $p < .05$ ($d = .95$).

Additionally, working alliance is rated as significantly higher for experienced supervisors [$F_{(2,30)} = 10.15$, $p < .05$, ($d = 1.64$)], with high allegiance [$F_{(1,31)} = 9.86$, $p < .05$ ($d = 1.12$) and [$F_{(2,30)} = 5.02$, $p < .05$ ($d = 1.15$)], who unconditionally accept themselves [$F_{(1,31)} = 9.86$, $p < .05$ ($d = d = 1.12$)] and who have a higher self-efficacy [$F_{(1,31)} = 9.86$, $p < .05$ $d = 1.12$].

Conclusions and discussion

As hypothesized, we found that supervisors' characteristics seem to play a major role when evaluating their trainees' outcome (level of unconditional self-acceptance, execution of the shame attack exercise). Our results show that experienced supervisors have better results in conducting personal development groups. Also, the more they believe in the efficiency of CBT in general and of the shame attack exercise in particular, the better the outcomes of their trainees. Trainees not only have better outcomes in these particular cases, but they also appreciate their working alliance with their supervisor as better than trainees who participated in groups lead by less experienced supervisors or with lower levels of allegiance, self-efficacy and unconditional self-acceptance.

The present study is not without limitations. In light of the small sample size, all findings in this study should be interpreted with caution. Thirty three trainees is not a small sample; however, in order to generalize our results to trainees in general, more data are needed. Additionally, though very interesting and rather innovative, results should be carefully interpreted. Clearly, supervisors' characteristics seem to play a major role in their trainees' outcome. A possible explanation for their interrelation may be that experience could actually be a valid explanation for some of the other results: it may very well be the case that the more supervisors treated patients over the years, the more they believed in the efficiency of CBT or of particular techniques, the more confident they felt about their competence and the more they unconditionally accept themselves.

Our study offers an important starting point for further research: we did find clear indications that supervisors' characteristics do seem to have an important role in trainees' outcome. Future studies might try to replicate the present results on larger samples and complement them by investigating more extensively other relevant characteristics (of both trainees and supervisors).

In conclusion, this study showed that supervisors' unconditional self-acceptance and self-efficacy seem to play an important role in delineating trainees' outcome: the more supervisors accept themselves unconditionally and the more they believe in their ability to be efficient therapists, the better their trainees' outcomes are. The implications for this study, as well as other similar research, may be essential not only for psychotherapy research literature but also for psychotherapy practice and training in psychotherapy.

[6]**STUDY 6. INVESTIGATION OF THE COURSE OF CHANGE IN A RCT FOR ADHD. ELABORATION OF A SOFTWARE PREDICTING RESULTS IN ADHD TREATMENT**

Introductory remarks

The need for ongoing monitoring of patient progress and appropriate adjustment of treatment has been reinforced by the APA's 2005 taskforce for evidence based practice in psychology (EBPP, APA Presidential Task Force on Evidence-Based Practice, 2005). There are several ways in which a therapist can monitor the progress of his patients. The scientist practitionner approach to psychotherapy has offered a valuable theoretical paradigm that can guide clinical practice (David, 2004). One can use various clinical instruments in order to assess client's current state; single case experiments or systematic observations are just few of the handy tools one can use without too much hassle. During the last decade, technological developments have brought important contributions to psychotherapy assessment, intervention and rehabilitation. To date OQAnalyst, based on the Outcome Questionnaire (OQ), developped by Lambert et al. (1996), is one of the most extensive software platforms designed to track treatment outcome. To detect significant change following a specific intervention, a statistical principle is then used. Thus, given the psychometric properties of OQ and the test scores of a target population, the software compares a patient's rated progress with the expected rate of improvement and uses empirically based algorithms to predict treatment gains or failures. This same principle was followed to develop the software application in the current study for predicting treatment outcome in patients diagnosed with Attention Deficit/Hyperactivity Disorder (ADHD).

A Randomized Clinical Trial in the Treatment of ADHD

ADHD is one of the most prevalent and severe psychiatric disorders from child and adolescent pathology range, being characterized by an extreme pattern of inattention, impulsivity and hyperactivity. ADHD affects 8% to 10% of children (Baren, 2002) and persist during adolescence in approximately 80% of cases (Schubiner et al., 1996). ADHD is largely considered a childhood disorder, with most patients being diagnosed during childhood.

Data used for this project are part of a randomized clinical trial (RCT) investigating the efficacy of Cognitive-Behavioral Therapy (CBT) versus medication and a combined condition for treating ADHD (David et al., in preparation). Children diagnosed with ADHD were recruited between 2006 and 2009 and were randomized in one of the three treatment groups: (1) CBT; (2) Medication – Atomoxetine; or (3) CBT + Medication. We will further concentrate on the first of these three groups.

The current study

Our main objective was twofold. First we aimed to explore the course of change of ADHD patients during CBT treatment. Then, based on formulas derived from empirical data, our goal was to develop a software program that not only tracks changes but also predicts estimated progress and gives feedback. In other words, the main idea

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[6] This study has been published.

was to develop a software program based on empirical data gathered in a randomized clinical trial that would offer users valuable data regarding their patients' past, present and estimated progress.

Method

Procedure

The data used for the software development were collected from the 20 patients who participated in the RCT undergoing psychotherapy. Patients were aged between 6 and 12 years old and were all diagnosed with ADHD (inattentive, hyperactive or combined). Their parents and teachers filled in several measures after the 1st (T0), 4th (T4), 8th (T8), 12th (T12) and 16th (T16) session of CBT.

The formulas for predicting treatment progress and outcome were statistically generated and were based on computational algorithms using SPSS.

The main rationale and steps followed in the process of algorithm development are indicated as follows:
1. The magnitude of change was calculated for each subject, at each moment (T4, T8, T12 and T16), for each outcome (CBCL and TRF) by reporting in treatment scores to scores at enrollment (T0).
2. The optimal linear function was identified in order to predict the magnitude of change at post treatment (T16-T0), for each moment (T4, T8, T12 and T16) and for each outcome (CBCL and TRF): (a) We explored correlations between change at each assessment moment and total change; (b) We performed regression analyses in order to identify the optimal predictive model by introducing variables in the regression model in a descending order of their correlation coefficients until an optimal model was reached; (c) The final linear prediction function was elaborated (the constant and the unstandardized regression coefficients).

Measures

Within this study the predictions on treatment progress and outcome are based on the patients' scores after the 1st, 4th, 8th, 12th and 16th session on the following scales: *Child behavior check list* (CBCL, Achenbach & Rescorla, 2001) is a standardized questionnaire used by parents or caregivers to rate the frequency and intensity of behavioral and emotional problems showed by their children during the past six months. *Teacher's report form* (TRF, Achenbach & Rescorla, 2001) includes items that are similar with the CBCL and is filled by teachers who have seen the student in classroom context for a period of a minimum of two months, as the ratings are done for the last two months. *DuPaul's ADHD Rating Scale* (ADHDparent, ADHDprof, DuPaul, 1991) includes parent's and teacher's ratings of ADHD symptoms. Each of the two scales includes 14 items designed to measure the components of ADHD: impulsivity, hyperactivity and inattention. A growing research literature has attested the validity of this measure (Power et al., 1998; DuPaul, 1991; DuPaul et al., 1998).

Results

Treatment outcome

Paired samples t test indicated significant differences between pre and post intervention for both measures assessing ADHD symptomatology: for TRF t(19) = 2.91,

p < .05, d = 0.91 and for CBCL t(19) = 5.70, p < .05, d = 1.47. These data confirm a significant amelioration of ADHD symptoms after CBT treatment with a large effect.

Course of change

Once we established ADHD symptoms were significantly reduced after a 16 week CBT intervention, we were interested in seeing what was the course of change. In addition to knowing whether post treatment scores are significantly reduced when compared to pretreatment measures, we were also interested in finding out if and when does change begin/cease to be significant during treatment. Paired simple T test were performed in comparing TRF and CBCL at T0 with T4, T4 with T8, T8 with T12 and T12 with T16. Results indicate significant decreases in symptoms, as measured by CBCL between the first and the 4th session t(19) = 4.80, p < .05 d = 0.62; significant amelioration in symptoms is also yielded between the 12th and the 16th session, t(19) = 3.31, p < .05 d = 0.83 In other words, most change occurs at the very beginning and very end of treatment.

When measuring symptoms with TRF, results show a slight decrease in symptoms during the first 8 weeks; however, no significant amelioration is noted. Between the 8th and the 12th session data show a significant deterioration, t(19) = -2.49, p < .05, d = -0.59. TRF scores significantly decrease during the next weeks, therefore results indicate a significant amelioration when comparing scores at the 12th and 16th session, t(19) = 3.28, p < .05, d = 0.92.

The software's predictive functions

As change was the main rationale for all predictive models, we first computed differences (Δchange) between CBCL and TRF at all assessment times during treatment and their values at baseline. Further on, predictive models were calculated. Knowing the course and the magnitude of change, algorithms were calculated in order to predict final results based on intermediate raw scores.

The software's clinical feedback

Clinical significance of a treatment represents "its ability to meet standards of efficacy set by consumers, clinicians and researchers" (Jacobson and Truax, 1991) and it refers to the practical or applied value or importance of the effect of the intervention - that is, whether the intervention makes a real (e.g., genuine, practical, noticeable) difference in the everyday life of the clients or of others whom the client interacts with (Kazdin & Weisz, 1998; Kazdin & Nock, 2003). The most popular strategy to investigate clinical significance was introduced by Jacobson et al. (1984) and developed by Jacobson and Truax (1991). The authors use the concept of „reliable change" and calculate a Reliable Change Index (RCI) for each individual, The authors consider that a change for a specific patient is reliable and the individual can be considered improved if RCI is higher than 1.96 and if this change is in the desired direction. Thus, we based a "traffic light" feedback on these formulas, as follows: green light if RCI > +1.96, yellow light if -1.96 ≤ RCI ≤ +1.96 and red light if RCI < -1.96. Our RCI is calculated based on the difference between the baseline and the predicted value of outcome at posttreatement (T16).

Software development

Based on previous results and analyses, we elaborated a software program that predicts treatment progress and outcome in patients undergoing CBT for ADHD. The

software is designed for clinical practice use and is free of charge (the first author can offer more details about the software as well as access, upon request; for an illustration please see Diagram 1).
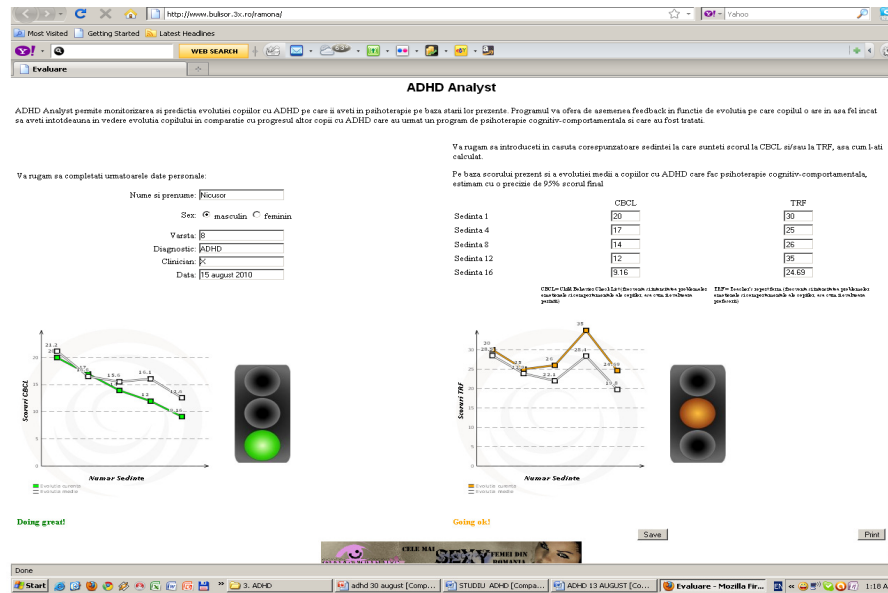
Diagram 1. ADHD Analyst

The software is a secured browser based application developed in JavaScript, which can easily be accessed from any PC, the only minimum requirement being an internet connection. The application provides a very intuitive interface. The main page displays on the left several text boxes for entering the identification data of the therapists and patients (i.e. name, gender, diagnosis, age, date). On the right, there are text boxes for entering the patients' scores on both scales CBCL (Child Behavior Check List) and TRF (Teacher's Report Form) after the 1st, 4th, 8th, 12th and 16th sessions. Once the clinician introduces the test scores of the patient, instant feedback is provided below as a graph of score tendencies accompanied by a traffic light. The 3 feedback categories corresponding to the traffic lights indicate if the patients' condition is improving, not changing or getting worse.

Thus, if a green light appears on the screen the message below the graph is that the patient is doing great, which means a reliable change in the desired direction. If the traffic light is yellow it means that the patient condition is not significantly changing. If the traffic light is red, an alert message is shown indicating that the patient's condition is getting consistently worse and immediate actions must be taken by the therapist.

Conclusions and discussion

These last several years, a tremendous development of artificial intelligence has been acknowledged. Starting with the 1980es, the integration of new technological developments (e.g., computer technology) into the therapeutic process has been a constant and increasing presence. New and innovative methods through wich artificial intelligence meets clinical psychology and psychotherapy have been brought into clinicians' attention. Their contribution to the advancement of the evidence-based movement, by increasing the clinical

expertise and by tailoring interventions to patient characteristics and accurate feedback makes them highly valuable instruments in the mental health field.

The main goal of our paper was to present and discuss the applications and advantages of computer technologies in psychotherapy assessment and intervention, using CBT as a general example, and the development of software for ADHD as a specific example.

The major implication of tools such as software programs aimed at predicting treatment progress and outcome is both to assist less experienced therapists and to complement the skills of well-trained clinicians (David, 2010). To a certain degree, they can also be regarded as means of putting to test the effectiveness of treatments that proved to be efficacious in RCTs.

CHAPTER 4
GENERAL CONCLUSIONS AND DISCUSSION

General comments

Enormous progress has been made in psychotherapy research. A large body of evidence clearly shows that (Reed & Eisman, 2006; Lambert & Archer, 2006; Norcross et al., 2006; Wampold, 2001; Lambert & Ogles, 2004; Chiles, Lambert, & Hatch, 1999): (1) Psychotherapy is generally effective, with positive outcomes reported for a wide variety of theoretical orientations and treatment techniques; (2) Although there is some variability across disorders, the effects of psychotherapy are generally as good as or, in some particular cases, superior to the effects of psychotropic medications; (3) The outcomes of psychotherapy are substantial across a variety of relevant areas, including emotional and behavioral symptoms, interpersonal functioning, social role performance, and occupational functioning; (4) The outcomes of psychotherapy are likely to be maintained over time, particularly in contrast to the effects of psychotropic medications; (5) Psychotherapy may offset the costs of medical services by reducing hospital stays and other medical expenses.

Researchers have hypothesized a number of different "active ingredients" that may be responsible for the therapeutic improvement. Traditionally, plausible active ingredients have been classified into two broad categories, *common factors* and *specific factors* (Castonguay, 1993; Webb et al., 2010).

Specific factors refer to the core, theory-specified techniques or methods that are prescribed for a given treatment modality (Castonguay & Holtforth, 2005). For instance, cognitive techniques (i.e. helping patients identify and challenge maladaptive thoughts) are ,according to cognitive therapy theory, central components of the treatment and play a key role in contributing to symptom improvement (DeRubeis, Webb, Tang, & Beck, 2009). Specific factors are, or should be, most often approached as mediators.

Common factors refer to those elements of therapy that are not unique and that are shared across most, if not all, therapeutic modalities (e.g., expectations of improvement, therapeutic alliance). Common factors are the essential ingredients of change that operate across different clients, problems, settings, and theoretical models. These elements are also referred to as "nonspecific factors" because they operate across all theoretical approaches and are not specific to any one particular model. Common factors are most often addressed as (non-specific) predictors of outcome.

Our research

Despite the fact that there is a high consensus that psychotherapy is effective and a broad agreement that outcome is explained by both general and specific factors, there is less agreement as to for whom, under what conditions and how psychotherapy works. Theory and

research in this area have been less focused on developing a systematic approach to understanding predictors of outcome in psychotherapy. Being aware of what implications psychotherapy has, and will have even more in the future, the current research, although modest in the context of a vast scientific literature, aimed to take the next step toward a cohesive approach of predictors of outcome (common and specific) in psychotherapy research.

Conclusions and implications of studies

Specific factors (Studies 1 and 2)
Study 1 : The aim of the this study was to identify and assess the impact of mediators in cognitive-behavioral psychological interventions on the outcome; particularly, we aimed (1) to estimate the overall effect size of various mediators in CBT and (2) to compare effect sizes in terms of the nature of mediators identified. Our main inclusion criteria were: randomized clinical trials investigating the role or mechanisms of cognitive behavioral based interventions; a clearly defined cognitive behavioral based intervention; the inclusion of a control group; and a clear mediation analysis of one or several variables on the outcome. Our analysis indicated a significant global mediation effect of cognitions on the outcome. Results indicate a low to medium effect size of cognitive mediators on the outcome, at post treatment. We then compared effect sizes by the nature of mediators (evaluative and non-evaluative). As a conclusion, analyses indicated a significant mediation effect of cognitions on the outcome. Even though this indicator has a low to medium effect and explains only 4% of the outcome variance, it clearly points to a cognitive mediation of symptoms and, consequently, of outcome results. Interestingly, non-evaluative cognitions have a low but significant effect on the outcome; specifically, they explain 3% of the outcome variance. Evaluative cognitions have a medium and significant effect on the outcome – they explain 8% of the outcome variance. Although there are no significant differences between evaluative and non-evaluative cognitions, in terms of effect, the direction of the differences is consonant with previous literature.

Study 2: The aim of this study was to empirically investigate cognitive mediators. In order to do this, we conducted a randomized clinical trial investigating the efficacy of cognitive bibliotherapy for adults with mild depressive symptomatology by comparing cognitive bibliotherapy with placebo, delayed treatment and natural evolution conditions. Analyses were first concerned with treatment outcome: cognitive bibliotherapy was superior in terms of outcome (depressive symptoms) as well as mechanisms (dysfunctional attitudes, automatic negative thoughts and irrational beliefs) when compared to delayed treatment and natural evolution conditions; cognitive bibliotherapy was superior to the placebo condition in terms of mechanisms, but not as far as the outcome is concerned. Results indicate that psychological treatment leads to both decreases in depressive symptoms and cognitive mechanisms while psychological placebo only leads to a decrease in symptoms. The results were statistically and clinically significant, and the treatment group maintained their levels of improvement at 3-month follow-up. Additionally, depressive symptoms significantly increased at 3-month follow-up for the placebo group. Analyses then concentrated on whether cognitive mechanisms mediate change in depressive symptoms. Automatic thoughts were found to mediate the impact of cognitive biliotherapy on depressive symptoms.

Studies 1 and 2. Conclusions and implications: Both studies were aimed at investigating, the first from a theoretical point of view and the second from an empirical perspective,

mediators in cognitive and behavioral psychological interventions. Mediators identified in the first study were included into the following categories: (1) automatic thoughts; (2) anxious self-statements; (3) attributional style; (4) catastrophizing; (5) coping; (6) estimated social cost; (7) dysfunctional attitudes; (8) fear of fear; and (9) hopelessness. They proved to have medium effects on the outcome; when comparing evaluative and non evaluative cognitions, the latter had a higher size effect. Our second study was particularly focused on the mediational role of mediators previously identified; the mediational effect found here was comparable to that previously identified in the meta analysis. Having these results in mind we can conclude that, in line with previous research, even though cognitive mediators have a medium effect in mediating the impact of cognitive and behavioral interventions on the outcome, it clearly points to a cognitive mediation of the psychotherapeutic change. Moreover, these results also indicate that there are several other factors influencing the outcome – most likely, they are non specific factors. Such factors could refer to working alliance, patient characteristics or placebo.

Common factors (Studies 3, 4, 5)
Study 3: This study was structured around several objectives. First, we wanted to investigate in a randomized clinical trial, the efficiency of one session treatment using Virtual Reality + Cognitive and Behavioral Therapy in treating social and specific phobia (heights and plane); here, we were interested in clarifying not only if treatment works (both in terms of outcome and mechanisms), but also if and to what extend do working alliance, patients' expectations and therapists' performance contribute to this change. Analyses revealed no significant differences between the immediate and the delayed treatment at post treatment. Analyses further indicated that while no significant differences were identified for general measures (such as anxiety, irrational beliefs), except for acrophobia, all other results indicated significant differences between measures when investigating the course of change from prior to post treatment. In investigating the impact of expectations, data indicate significant associations between expectations and most outcome changes. Expectations have a low to medium effect size in explaining changes in rational and irrational cognitions and reduction of fear during the intervention. Further analyses indicate that working alliance (assessed by the patient) has a medium effect size in explaining rationality and irrationality change in patients, as well as change of anxiety symptoms during treatment. Another important result of our study was that the therapists' performance had a significant impact in accounting for change in anxiety symptoms during psychotherapy.

Study 4: The aim of the this study was to investigate the extent to which therapists' expectations and self-efficacy impact on their performance; further on, our aim was to examine the effects of therapist performance in conducting a relaxation exercise on the exercise efficiency. Contrarily to our assertions, our hypotheses presuming self-efficacy and expectations to be correlated with performance were not confirmed by our data. However, results indicate that therapists' performance significantly explains the variance of relaxation reported by volunteers. More specifically, therapists' performance has a medium effect size in explaining the efficiency of relaxation.

Study 5: The main objective of this study was to investigate whether and to what extent a good working alliance must be present when therapists in training are in supervision and/or personal development sessions; we also wanted to investigate what are the predictors of the working alliance. As hypothesized, supervisors' characteristics seem to play a major role when evaluating their trainees' outcome. Our results show that experienced supervisors have

better outcomes in conducting personal development groups. Also, the more they believe in the efficiency of CBT in general and of the personal development exercise in particular, the better the results their trainees have. Unconditional self-acceptance and self-efficacy also seem to play an important role in delineating trainees' performance: the more supervisors accept themselves unconditionally and the more they believe in their ability to be efficient therapists, the better their trainees' outcomes are.

Studies 3, 4 and 5. Conclusions and implications: These three studies were aimed at investigating common factors in cognitive and behavioral psychological interventions. Working alliance was confirmed to be an important contributor to the outcome and had a medium effect size in explaining rationality and irrationality change in patients, as well as change of anxiety during treatment. Expectations, both therapists' and patients', have a low to medium effect size in explaining changes in rationality and irrationality as well as anxiety. Therapists' performance is another predictor with a significant impact on change. Data also show that, when unexperienced, therapists' expectations and self-efficacy regarding their performance do not correlate with their actual performance; however, once again, therapists' performance is a good predictor of the outcome. For experienced therapists, performance is associated with allegiance, self-efficacy, unconditional self-acceptance and experience.

Course of change (Study 6)
Study 6: Our first objective was to initially explore the course of change of ADHD patients during CBT treatment. Then, based on formulas derived from empirical data, our goal was to develop a software program that not only will track changes but will also predict estimated progress and give feedback. Results indicated significant differences between pre and post intervention for in terms of ADHD symptoms. Based on these results and the algorithms that were derived, a software program was developed.

Study 6. Conclusions and implications: ADHD Analyst is the first software application designed to measure treatment progress and outcome for ADHD. The major implication of tools that are aimed at predicting treatment progress and outcome is that they can be regarded as means of putting to test the effectiveness of treatments that proved to be efficacious in RCTs. The software stores all patients' data and allows the clinician to see at any time the progress status of the patient after each of the five assessment sessions; one can also choose to print reports. The software application is able to detect at what stage in therapy most significant progress was made by the patient, or on the contrary, at what stage did the treatment stop adding gains, or if the patient stopped responding to treatment.

Final remarks about the studies
There are several "take home" messages following the studies that have been undertaken throughout this research project.
1. Cognitions seem to mediate the effect of Cognitive and Behavioral Therapies on the outcome. Having a medium effect on the outcome, we can conclude that current research clearly points to a cognitive mediation of the outcome. More specifically, evaluative cognitions seem to have a higher effect than non evaluative cognitions. Data also ahow that there are several other factors influencing the outcome; these factors are, most likely, not specific to cognitive and behavioral therapies.
2. Working alliance (interestingly, only when rated by patients) is a strong predictor of the change occurring during cognitive and behavioral therapy (both in terms of symptoms and mechanisms).

3. Patients' expectations predict change occurring during cognitive and behavioral therapy (both in terms of symptoms and mechanisms).
4. Therapists' performance has a significant impact in accounting for change in the outcome occurring during psychotherapy. Therapists' performance also has a significant role in predicting the outcome of a specific technique performed by the therapist.
5. Inexperienced therapists' self-efficacy and expectations are not associated with their performance and the outcome.
6. Experienced therapists have higher allegiance, higher self-efficacy, and higher level of unconditional self-acceptance and have better working alliances with therapists in training as well as better outcomes to what these are concerned.

Personal contributions

In addition to the valuable empirical data brought to this area of research and to the potentially complex questions for the practice of psychotherapy, there are several personal contributions that are important to mention.
1. To our knowledge, the meta-analysis we conducted is the first to address mediators in cognitive-behavioral psychological interventions in general. There are a number of papers investigating the impact of various mediators on the outcome, but no quantitative meta-analysis has been conducted so far to investigate specific variables mediating the impact of CBT on the outcome and to estimate their effect sizes.
2. The randomized clinical trial we undertook investigating the efficacy of cognitive bibliotherapy for adults with mild depressive symptomatology by comparing cognitive bibliotherapy with placebo, delayed treatment and natural evolution conditions not only brought valuable empirical support to existing data but is, to our knowledge, the most comprehensive randomized clinical trial to date conducting longitudinal mediation. The study also has some ingenious methodological aspects allowing drawing conclusions in terms of getting better and feeling better theory, which doesn't have much empirical support to date.
3. The randomized clinical trial investigating the impact of one session treatment of Virtual Reality + Cognitive and Behavioral Therapy is in itself innovative as no such study for social and specific phobia is available. An important contribution of this study is that it addresses simultaneously psychotherapy components such as working alliance, patients' expectations and therapists' performance.
4. To our knowledge, there is no previous research investigating the relation between self-efficacy, performance and outcome for both experienced and inexperienced psychotherapists.
5. ADHD Analyst this is the only coherent software developed to track patients' progress and predict their treatment outcome.

Directions for Research, Practice, and Training

A scientific approach to psychotherapy requires an appreciation of this area not only as it is but also as it should be. Henceforth, a scientific approach to psychotherapy requires an appreciation of the various forms of psychotherapy not only as they are but also as they should be.

The scientific study of mechanisms of change is certainly not an easy path on which to embark. A given treatment might work for multiple reasons. This kind of research is in its infancy, evident from the fact that no definitive mechanisms of change for any type of psychotherapy have been satisfactorily demonstrated. Interesting patterns are appearing,

particularly within the field of cognitive psychotherapy. The replication of mediator findings will strengthen the argument for any given mediator. Studies aimed at directly manipulating potential mediators can contribute further to our understanding of the mechanisms at work in psychotherapy (Owen et al., 2009)

Undoubtedly, more studies need to be conducted, across a variety of different treatment modalities, in which other process variables, such as therapist adherence and competence, are examined in relation to outcome. Additional studies investigating adherence–outcome and competence–outcome relations would also provide for more statistically powerful meta-analytic reviews.

This research is a step toward enhancing our understanding of common and specific factors involved contributing in the outcome. We hope that this effort stimulates further research and dialogue on the importance of these aspects.

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