

A TRANSDIAGNOSTIC INTERVENTION PROGRAM DELIVERED
ONLINE IN ANXIETY AND DEPRESSION: A RANDOMIZED
CONTROLLED NON-INFERIORITY TRIAL

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Abstract

Background and Aims: In the last years, the therapeutic programs delivered online have started to develop more and more. However, there are not many clinical trials that have compared the effectiveness of two clinical interventions, both delivered online. The primary aim of this study was to investigate the efficacy and acceptability of a guided internet delivered transdiagnostic intervention, targeting mild to moderate clinical symptoms of anxiety and depression and emphasizing the changes taking place at the level of the structures of the self. The secondary aim was to compare this intervention with a “golden standard” transdiagnostic intervention in anxiety and depression in a randomized non-inferiority trial.

Method: A total of 284 participants were randomly assigned to one of the two interventions. The effectiveness of a transdiagnostic cognitive-behavioral treatment was compared with an another version of it, in which new intervention techniques were added, pointing out the importance of improving some self-concept dimensions in reducing symptoms of anxiety and depression. In order to prove this, the study design included two active intervention groups.

A standard transdiagnostic intervention protocol was delivered to one group (n=141) and an improved version of the same transdiagnostic protocol was delivered to the other group (n=143). The new added techniques targeted some self-concepts, namely self-compassion, unconditional self-acceptance and self-esteem. So the main goal of the study was to concurrently test effectiveness of these two transdiagnostic approaches in reducing symptoms of anxiety and depression and improving the above-mentioned self-concepts.

Results: Both intention-to-treat and completers analysis yielded no significant between-group difference for any of the post-interventions measurements. At post-treatment both intervention conditions revealed significant symptom changes compared to before the intervention. Within-group effect sizes for anxiety (GAD7) in one intervention group ($d=0.92$) and in the other intervention group ($d=1.28$) can be considered large. Within-group effect sizes for depression (BDI-II) in one intervention group ($d=1.34$) and in the other intervention group ($d=1.47$) can also be considered large. At 6-months follow-up, results remained stable in both intervention groups.

Conclusions: We did not find statistically significant differences between the two intervention groups in either the post-test or follow-up measurements, so the increase in the level of self concepts occurs in both situations: if we make a direct intervention in this regard or if we conduct a classic intervention in clinical anxiety and depression.

Cuvinte-cheie: intervenție cognitiv-comportamentală, anxietate, depresie, sine, intervenție online.

Keywords: cognitive-behavioral intervention, anxiety, depression, self, online intervention.

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1. INTRODUCTION

Anxiety and depression are some of the most common mental disorders among adults. They are frequently associated with significant impairments in health and functional status, as well as with high economic and personal costs. Anxiety disorders includes those perturbations that have in common the excessive fear and associated behavior disruptions (DSM-5). The fear represents the emotional answer to a real or supposed imminent danger, while the anxiety represents the anticipation of a risk or danger. Sometimes the anxiety level is attenuated through a pervasive avoidance behavior. Depression on the other hand includes the presence of a sad mood, inner void and irritability, together with somatic and cognitive alterations which significantly affect the individual ability of functioning (DSM-5).

For both of these disturbing conditions, the early age of onset, the highly prevalence rate and the long-term nature of disorder make them a major public health problem that generates large direct and indirect costs for the persons involved as well as for the whole society. The problem is that the majority of these suffering people do not access treatment. Barriers to access effective treatment include lack of time because of long waiting time, geographic distance to mental health services, fear of stigma or unwillingness to disclose psychological problems (Collins *et al.*, 2004). Internet-delivered interventions may be the solution to all these obstacles, especially because face to face therapy is dependent on the availability of much more trained therapists. Guided Internet-based Cognitive Behavior Therapy has already shown promising results in randomized controlled trials conducted by independent research groups, for example in general anxiety disorder and social anxiety disorder (Furmark *et al.*, 2009; Berger *et al.*, 2009) and for depression clinical conditions a meta-analysis including data from 25 controlled trials supports also these previous findings about the good effect sizes of Internet delivered interventions (Johansson and Andersson, 2012). For all the above, we have also chosen to deliver online interventions for anxiety and depression in the non-inferiority trial from this study.

Another aspect that we took into account, was the impact of the self dimensions on the intensity of the anxiety and depression symptoms. There are different studies that showed that some self-concepts, for example: self-esteem, self-compassion, self-efficacy, unconditional self-acceptance and self-concept clarity have a protective role in clinical psychological conditions.

A meta-analysis including data from 77 longitudinal studies about depression (Sowislo & Orth, 2013) has found much more empirical proves in favor of the effect that self-esteem has on depression than depression on self-esteem. Also, Evraire and Dozois (2011) have created a new integrative model that explains the appearance and maintaining of depression through excessive seeking of the encouragement and negative feed-back, which are two mechanisms that are representative to people with low self-esteem. Another variable in this self-equation is self-compassion which represents the ability of being kind and sympathetic

towards one's own person, even in life situations that include suffering or failure (Neff, Kirkpatrick & Rude, 2007). The unconditional self-acceptance represents a protective element against emotional difficulties (Woodruff, 2014), including depression (Diedrich *et al.*, 2014). From the social-cognitive perspective, the self-efficacy represents another key variable for explaining psychological disorders. In 2003, Albert Bandura has introduced the concept of beliefs in personal self-efficacy in managing emotions, with a role in emotional regulation, as a specific branch of self-efficacy. In this way it can be measured the people's belief in their ability to regulate their own emotions, with a specific subcomponent regarding their effectiveness in regulating negative emotions. Caprara *et al.*, 2010 have found a significant direct link between self-efficacy in managing emotions and depression, in a prospective four-wave study. Campbell *et al.*, 1996 have introduced the notion of self-concept clarity that represents the extent to which the person's concepts about the self (for example, the perceived attributes) are clearly and precisely defined and stable. Bleidorn and Koding (2013) summarized the results in a meta-analysis, which shows that the lack of clarity about the self (the presence of a fragmented or divided self) is positively correlated with depression.

For all these reasons, we have developed an intervention program for anxiety and depression, for clinical and subclinical conditions, emphasizing through some techniques these above self components. The starting point was represented by the golden standard protocol developed by Professor Barlow and his clinical team: Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (Farchione *et al.*, 2012). Prior to this study, we have conducted a longitudinal study that has showed that the self-views are good predictors for the level of anxiety and depression. So our whole therapeutic program had two intervention arms: one was the Barlow Unified Protocol itself and the other one included this protocol as well as specific techniques targeting the self-views: self-esteem, self-compassion, self-efficacy, unconditional self-acceptance and self-concept clarity.

The techniques for self-views were adapted from ACT, Acceptance and Commitment Therapy, a psychotherapy that is largely based on the Buddhist philosophy, which has as its main purpose the human's ability to look at life with detachment or at least without deep attachment. This life perspective is quite difficult to integrate for the first time and for some participants these particular applications needed extra explanations at the beginning. They have never thought before about seeing life through these filters, which also required a certain level of culture and a certain wisdom.

Any in-depth therapeutic process produces changes in the inner self. There is no way to progress and overcome difficult life situations without self-restructuring. Adaptation to daily life involves self-adaptation. Otherwise, we would perform far too many irrational and maladaptive behaviors. For this reason, there are these improvements in self parameters in both treatment groups. Bending over one's self-decipherment is a major benefit and an important protective factor in the face of clinical symptoms.

2. METHOD

2.1. ETHIC STATEMENT

Ethical approval for the trial was given by the institutional review board of the West University from Timișoara. All participants received an informed consent via online before they answered to the screening questionnaires. The protocol for this trial is available as supporting information.

2.2. PARTICIPANTS AND RECRUITMENT

Potential participants were recruited from all over Romania, through advertisements in newspapers, radio and TV and online on personal Facebook walls and anxiety or depression self-help online groups. After their online registration with username and password on www.e-cbt.ro, they completed the online screening questionnaires in a self-reported manner.

The inclusion criteria were:

- be fluent in Romanian;
- be at least 18 years of age;
- have at least a clinical diagnosis of major depressive disorder/dysthymia, and/or generalized anxiety disorder, and/or social anxiety disorder, panic anxiety disorder and/or agoraphobia, specific phobia or any combination of these conditions on Structured Clinical Interview for the Diagnostic and Statistical Manual for Mental Disorders 5 (SCID 5).

The exclusion criteria were:

- suicidal plans;
- changes in the dosage if psychotropic medication during the last month (if present);
- suffering from bipolar disorder or psychosis (according to medication status);
- suffering from post-traumatic stress disorder or obsessive-compulsive disorder (according to medication status);
- suffering from an alcohol/substance abuse and/or dependence disorder;
- currently receiving other psychological treatment;
- obvious obstacle to participation (i.e., no current Internet access, long travel plans during the treatment period, etc.).

Selection of eligible participants had two phases: online screening questionnaires filling and a phone interview concerning anxiety and depression symptoms using the structured clinical interview SCID 5. Applicants who indicated they met the study requirements started the therapeutic program with the pre-test measures. These new questionnaires measured also the level of the self-concepts, such as:

self-compassion, self-esteem, unconditional self-acceptance, self-efficacy and self-concept clarity. Participants were randomly assigned by the study coordinator to one of the two active therapeutic programs. Further we will refer to these programs as: Self for the intervention focused on the self-concepts and PsiTad for the psychological treatment on anxiety and depression (the golden standard protocol).

The group of participants included in the program totalizes 284 people, from which 84.4% female and 15.6% male. Their age was between 19 and 67 years, with the average $M = 33.34$. Most of them found out about the recovery program through Facebook (59.7%), then for 25.5% the program was recommended to them by an acquaintance, and 5.7% found out from news or television shows.

Among the demographic characteristics of the participants included in the study we can mention the following: 43.3% had university studies, 28.9% had master degrees and 25.1% had theoretical or vocational high school studies. And in the extremes 1.1% (3 people) had primary school level studies and also, 3 people had doctoral level studies.

In terms of occupation, 56.3% of the participants were full-time workers, 25.1% were full-time students and 9.5% were housewives. Regarding the marital status, the situation was somehow equivalent: 37.3% were unmarried people and 32.7% were married people, only 11.4% were divorced people and one widow.

Regarding the existence of a previous diagnosis: 75.7% of the participants did not have a psychiatric diagnosis, and 24.3% have been to a psychiatrist in the past and received a specific diagnosis. Regarding the psychotropic medication: 91.3% of the participants did not have drugs prescription from a psychiatrist and only 8.7% were during a medication program.

The most important clinical diagnoses of the participants were: 16.7% generalized anxiety disorder, 28.5% major depressive disorder, 29.7% persistent depressive disorder, 12.2% panic disorder and 6.1% social anxiety disorder.

A total number of 1405 participants applied initially for the study and the whole process from selection till the follow-up is represented in the below flow chart (see Fig. 1).

2.3. PROCEDURE

Primary and secondary outcome measures were collected at pre-treatment, post-treatment and 6-months follow-up. All measures for both intervention groups were administrated through online questionnaires in a self-reported manner, excepted the initial phone interviews on SCID 5. A number of studies have shown that online format questionnaires produce results as valid as pen-and-paper questionnaires (Hollandare *et al.*, 2010). The 284 participants included in the study were randomized by a true random number service (<http://www.random.org>) using a 1:1 ratio, with 143 participants randomly allocated to the Self treatment group and 141 participants randomly allocated to the PsiTad group. Randomization was performed by the study coordinator and was not stratified by any participant's characteristics.

Study flow diagram

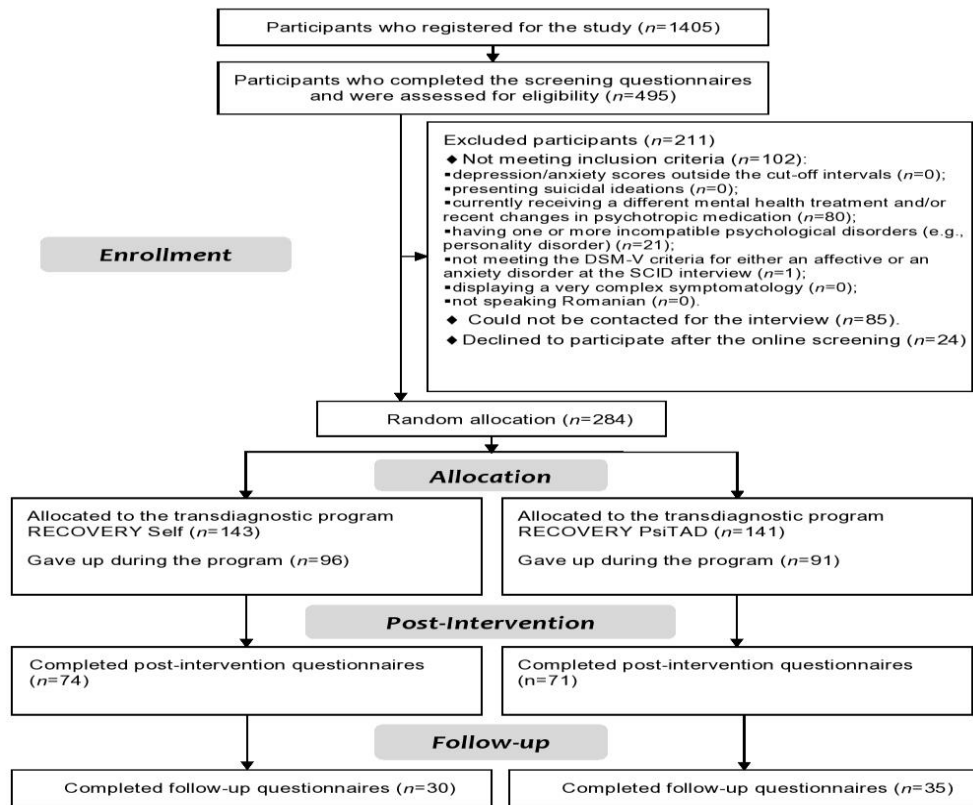


Fig. 1. Flowchart of patients participation.

2.4. INTERVENTIONS

The intervention protocol that was delivered was a transdiagnostic one, namely David Barlow's protocol "The unified protocol for transdiagnostic treatment of emotional disorders". Its central idea is that emotional disorders approach focuses on the similarities between emotions, rather than on their specificity in some clinical pathologies. This is happening because of a considerable resemblance of mind disorders phenomenology and of a common set of vulnerabilities that contribute to emotional disorders enlargement (Barlow *et al.*, 2011). Applying a unified protocol in emotional disorders treatment is a radical shift to continue using individual protocols, focused on specific emotional disorders. That's why this approach was projected to be applicable to all anxiety and affective disorders.

The program involved 9 modules, one a week. During the intervention, the participants had the opportunity to better understand their emotional condition, to succeed in accepting it unconditionally, to identify and restructure their automatic negative thoughts, but also to expose themselves during different exercises, which proved to be very useful in reducing the anxiety symptoms.

Pre-treatment, mid-treatment and post-treatment the participants were asked to complete the online screening questionnaires on anxiety, depression and self-concepts: self-compassion, self-esteem, unconditional self-acceptance, self-efficacy, and self-concept clarity. All the participants were helped during the treatment and they received positive reinforcements for each progressive step. They were also given personalized guidance to increase the treatment adherence and to encourage them to move on to the last module.

The intervention program was based on the following therapeutic strategies for depressive anxiety symptoms: (1) encouraging awareness of one's own emotional experience; (2) cognitive flexibility (cognitive restructuring); (3) improvement of maladaptive behaviors generated by emotions; (4) facilitating exposure to interceptive and situational parameters, associated with emotional experiences; (5) acceptance of intense physiological sensations.

The program involved the following CBT modules: (1) treatment motivation and goals setting for this program; (2) understanding and monitoring emotions; (3) observing our emotions and our reactions to emotions; (4) understanding the cognitive aspects: when you think about the worst and overestimate the risks; (5) avoiding emotions and trying to make everything perfect; (6) behaviors triggered by emotions; (7) confronting emotions in real life situations; (8) understanding and confronting the physiological sensations; (9) life after treatment: recognition of achievements and future plans.

This therapeutic program was delivered online to one of the intervention groups. The program was validated by David Barlow and his team. The other intervention group received a version of this program in which some explanations were replaced with specific applications for increasing the level of some self-concepts: the unconditional self-acceptance improvement; the self-compassion development; the self-esteem growth.

Both online interventions were given as guided interventions with intensive therapist contact, based on the therapy principles applied in a number of previous studies (Lange *et al.*, 2003; Ruwaard *et al.*, 2007; Ruwaard *et al.*, 2009; Wagner *et al.*, 2006; Hedman *et al.*, 2011). The time the therapist invested to respond to participants' texts was 20–50 minutes per text, depending on the therapist's experience with internet-based therapies. The patients were given assignments and homeworks every week and the therapists provided individual written feedback within one day, along with instructions and the module for the next week. The study coordinator offered model responses for the therapists, but they also had the option to provide their own commentaries or supportive feedbacks on their patients' texts.

2.5. THERAPISTS

The therapists were twelve young psychologists and psychotherapists under supervision and their study coordinator. All psychologists were trained in psychotherapy and Cognitive Behavior Therapy for anxiety and depression specifically for this study. The therapists received from the study coordinator a special training in therapeutic writing for the online treatment. Also they were given regular supervision (face-to-face or online) by the study coordinator.

3. OUTCOME MEASURES

Our outcome measures were collected at pre-treatment, post-treatment and 6-months follow-up.

3.1. PRIMARY OUTCOME MEASURES

Patient Health Questionnaire 9 (PHQ9, Kroenke, Spitzer & Williams, 2001) was designed to measure participant's level of depression. The scale is one-dimensional and the total score ranges from 0 to 27. Each item corresponds to a DSM5 diagnostic criteria for major depressive disorder and it is scored from 0 (not at all) to 3 (nearly every day). The higher the total score is, the more severe are the depression symptoms.

Generalized Anxiety Disorder 7 (GAD7, Spitzer *et al.*, 2006) was designed to measure participant's level of generalized anxiety or worry. The scale is one-dimensional and the total score ranges from 0 to 21. The scale is often used as a screening instrument for anxiety disorders (Kroenke *et al.*, 2007). Each item corresponds to a DSM5 criteria for generalized anxiety disorder and it is scored from 0 (not at all) to 3 (nearly every day). The higher the total score is, the more severe are the anxiety symptoms.

Social Phobia Inventory (SPIN, Connor *et al.*, 2000) was designed to measure participant's level of social anxiety. The scale is one-dimensional and the total score ranges from 0 to 68. The 17-item scale has very good psychometric properties (Connor *et al.*, 2000, Antony *et al.*, 2006) and can be considered an evidence-based outcome measure (Rowa *et al.*, 2008).

Panic Disorder Severity Scale-Self Report (PDSS-SR, Shear *et al.*, 2001) was designed to measure participant's level of panic symptoms. The scale is one-dimensional and the total score ranges from 0 to 28. The 5-item scale has good internal consistency and construct validity (Shear *et al.*, 2001).

3.2. SECONDARY OUTCOME MEASURES

Work and Social Adjustment Scale (WSAS, Mundt *et al.*, 2002) was designed to measure symptoms interference in work, home management, leisure and family relationships. The 5-item scale was successfully used in previous studies (Brown &

Barlow, 1995). The scale is one-dimensional and the total score ranges from 0 to 40. Low scores are associated with higher levels of functioning (less interference of clinical symptoms) while high scores are associated with lower levels of functioning (or higher interference of clinical symptoms).

Beck Depression Inventory-II (BDI-II, Beck *et al.*, 1996) was designed to measure participant's level of depression. The scale is one-dimensional and the total score ranges from 0 to 63. The 21-item scale is a widely used screening instrument of current depression. The data for scale's reliability and validity were reported in clinical samples (Beck *et al.*, 1996, Storch *et al.*, 2004) and the scale is also considered an evidence-based outcome measure (Person & Fresco, 2008).

Penn State Worry Questionnaire (PSWQ, Meyer *et al.*, 1990) was designed to measure participant's level of generalized anxiety or worry. The scale is one-dimensional and the total score ranges from 16 to 80. The 16-item scale has very good psychometric properties (Molina & Borkovec, 1994) and the scale is considered an evidence-based outcome measure (Gervais & Dugas, 2008).

Anxiety Sensitivity Index 16 (ASI 16, Reiss *et al.*, 1986) was designed to measure participant's level of anxiety sensitivity. The scale is one-dimensional and the total score ranges from 0 to 64. The 16-item scale assesses fear of anxiety-related symptoms. The instrument has a high internal consistency (Reiss *et al.*, 1986) and test-retest reliability (Maller & Reiss, 1992) and can be considered an evidence-based outcome measure (Keller & Craske, 2008).

Self-Concept Clarity Scale (SCCS, Campbell *et al.*, 1996) was designed to measure participant's level of their Self-Concept Clarity. The scale is one-dimensional and the total score ranges from 12 to 60. The 12-item scale was used to measure the extent in which an individual perceives that his personal beliefs and behaviors are coherent and stable across various roles, contributing to the clarity of the self-concept. Each item is scored from 1 (totally disagree) to 5 (totally agree). Most items need reverse scoring.

New General Self-Efficacy Scale (NGSE, Chen *et al.*, 2001) was designed to measure participant's level of Self-Efficacy. The scale is one-dimensional and the total score ranges from 8 to 40. The 8-item scale has each item scored from 1 (totally disagree) to 5 (totally agree). The higher the score, the higher the level of self-efficacy.

Unconditional Self-Acceptance Questionnaire (USAQ, Chamberlain & Haaga, 2001) was designed to measure participant's level of unconditional Self-Acceptance. The scale is one-dimensional and the total score ranges from 20 to 140. The 20-item questionnaire measures the extent to which people accept themselves independently of their self-evaluation. Each item is scored on a scale from 1 (almost always untrue) to 7 (almost always true). Some items need reverse scoring.

Overall Anxiety Severity and Impairment Scale (OASIS, Norman *et al.*, 2006) was designed to measure participant's level of overall anxiety. The scale is one-dimensional and the total score ranges from 0 to 20. The 5-item questionnaire

captures anxiety-related symptom severity and impairment across anxiety disorders and has good psychometric proprieties (Norman *et al.*, 2006, Norman *et al.*, 2011).

Overall Depression Severity and Impairment Scale (ODSIS, Bentley *et al.*, 2014) was designed to measure participant's level of overall depression. The scale is one-dimensional and the total score ranges from 0 to 20. It is also a 5-item instrument meant to measure severity and impairment of depressive symptoms. The scale demonstrated high internal consistency and good convergent and discriminant validity (Bentley *et al.*, 2014).

Rosenberg Self-Esteem Scale (RSES, Rosenberg, 1965) was designed to measure participant's level of Self-Esteem. The scale is one-dimensional and the total score ranges from 10 to 40. The scale is the most widely used 10-item instrument to measure self-esteem. Each item is scored on a scale from 0 (strongly disagree) to 3 (strongly agree). Five items need reverse scoring. The higher the total score, the more favorable people evaluate themselves.

Self-Compassion Scale (SCS, Neff, 2003) was designed to measure participant's level of their Self-Compassion. The scale is multidimensional and the total score ranges from 26 to 130. On the 26-item scale each item is scored from 1 (almost never) to 5 (almost always). The scale contains six subscales: self-kindness, self-judgment, common humanity, self-isolation, mindfulness and over-identification. Neff, Whittaker and Karl (2017) suggest that a total score could be used as an overall measure of self-compassion.

Automatic Thoughts Questionnaire (ATQ, Hollon & Kendall, 1980) was designed to measure depressogenic thoughts frequency. The scale can be used in depression studies to examine the impact of cognitive therapy. On the 15-item scale each item is scored from 1 (never) to 5 (almost always). We used a shortened version of the scale, which originally has 30 items, as its psychometric properties show strong internal consistency and validity (Netemeyer *et al.*, 2002).

Table 1

Alfa Cronbach fidelity coefficient for each instrument

Instrument	Alfa Cronbach	Alfa Cronbach based on standardized items	Number of items
BDI	.892	.896	21
USAQ	.861	.860	20
RSES	.910	.909	10
ODSIS	.931	.932	5
SCS	.894	.895	16
SCCS	.892	.894	12
NGSE	.935	.935	8
PHQ9	.852	.851	9
GAD7	.883	.885	7
PDSS	.921	.921	7

Table 1 (continued)

Instrument	Alfa Cronbach	Alfa Cronbach based on standardized items	Number of items
PSWQ	.904	.906	16
SPIN	.927	.927	17
WSAS	.818	.820	5
ASI	.921	.920	16
ATQ	.949	.949	16
OASIS	.877	.879	5

4. STATISTICAL ANALYSIS

4.1. RESULTS

The table with descriptive values below shows that there is a difference between the averages within each group, both in terms of decreasing clinical symptoms and in terms of increasing the values of the self-components. There is also a difference between the averages of those who completed the treatment (completers) and those who gave up along the way (intend to treat); those who reached the end have much better results.

Table 2

Descriptive values for each treatment group

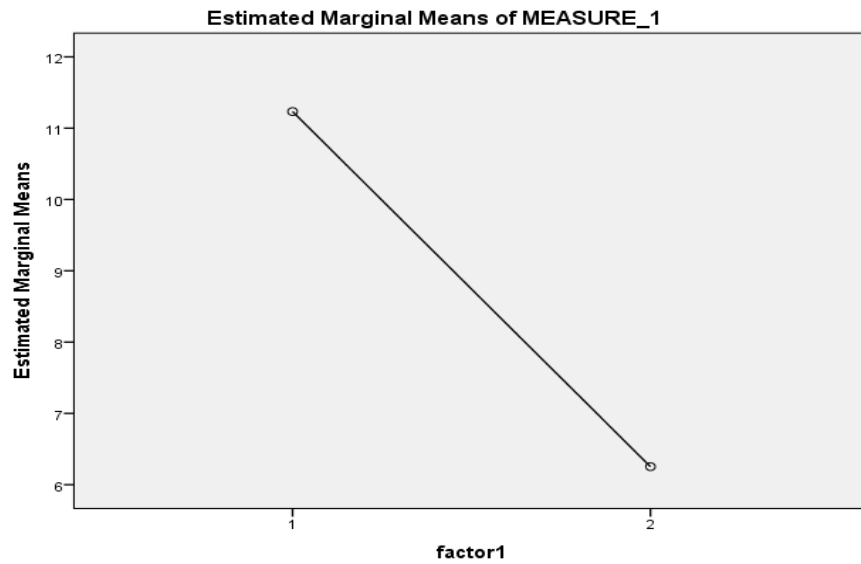
Outcome	Completers M (SD)		Intend to treatM (SD)	
	Treatment (n = 47)	Control (n = 50)	Treatment (n = 143)	Control (n = 141)
PHQ9				
Baseline	13.51 (6.04)	14.22 (6.26)	13.51 (6.04)	14.22 (6.26)
Post-intervention	7.39 (5.76)	6.97 (4.84)	10.43 (6.59)	11.27 (7.16)
SPIN				
Baseline	32.44 (14.55)	33.75 (14.30)	32.44 (14.55)	33.75 (14.30)
Post-intervention	24.55 (13.32)	21.93 (14.06)	27.66 (14.58)	27.78 (15.05)
PSWQ				
Baseline	61.99 (9.42)	62.29 (9.35)	61.99 (9.42)	62.29 (9.35)
Post-intervention	54.28 (10.90)	51.47 (10.37)	57.46 (11.07)	56.76 (11.49)
BDI-II				
Baseline	24.88 (10.17)	25.68 (11.31)	24.88 (10.17)	25.68 (11.31)
Post-intervention	11.06 (10.42)	10.42 (8.95)	18.09 (13.17)	18.51 (13.32)
BDI-II suicide				
Baseline	0.33 (0.53)	0.37 (0.59)	0.33 (0.53)	0.37 (0.59)
Post-intervention	0.15 (0.46)	0.10 (0.31)	0.23 (0.47)	0.26 (0.51)
WSAS				
Baseline	17.65 (8.23)	17.26 (8.75)	17.65 (8.23)	17.26 (8.75)
Post-intervention	10.51 (8.47)	8.97 (8.09)	13.77 (9.07)	13.77 (9.64)
PDSS				
Baseline	5.91 (5.93)	6.99 (6.24)	5.91 (5.93)	6.99 (6.24)
Post-intervention	3.81 (4.78)	3.16 (4.34)	4.73 (5.41)	5.24 (5.96)

Table 2 (continued)

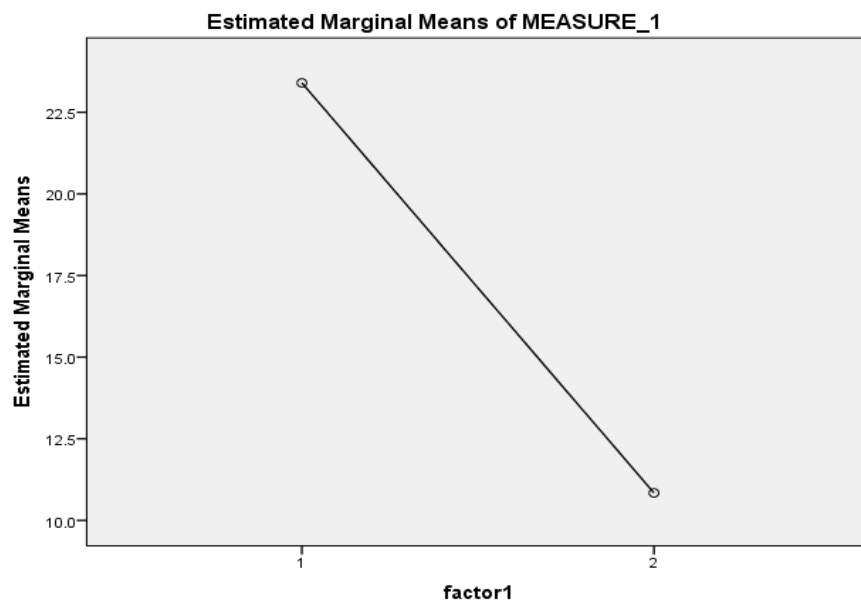
Outcome	Completers M (SD)		Intend to treatM (SD)	
	Treatment (n = 47)	Control (n = 50)	Treatment (n = 143)	Control (n = 141)
ASI				
Baseline	30.53 (13.84)	30.35 (13.77)	30.53 (13.84)	30.35 (13.77)
Post-intervention	23.99 (15.36)	19.91 (12.46)	26.24 (14.61)	26.23 (14.15)
GAD				
Baseline	11.67 (5.09)	12.22 (5.47)	11.67 (5.09)	12.22 (5.47)
Post-intervention	6.65 (5.74)	5.75 (4.53)	9.19 (6.09)	9.34 (6.10)
ATQ				
Baseline	47.61 (13.23)	47.21 (13.58)	47.61 (13.23)	47.21 (13.58)
Post-intervention	36.51 (15.91)	31.94 (13.59)	42.23 (16.03)	41.21 (16.07)
ODSIS				
Baseline	7.35 (4.38)	7.33 (4.94)	7.35 (4.38)	7.33 (4.94)
Mid-intervention	4.98 (4.18)	4.87 (4.24)	5.77 (4.52)	5.81 (4.66)
Post-intervention	3.68 (4.53)	3.18 (4.07)	5.28 (4.89)	5.40 (4.91)
OASIS				
Baseline	8.36 (3.89)	8.09 (4.19)	8.36 (3.89)	8.09 (4.19)
Mid-intervention	6.43 (3.71)	6.43 (3.21)	6.79 (3.87)	7.02 (3.68)
Post-intervention	4.91 (3.66)	4.28 (3.56)	6.11 (4.06)	5.99 (4.17)
USAQ				
Baseline	67.41 (16.71)	67.17 (17.99)	67.41 (16.71)	67.17 (17.99)
Mid-intervention	73.52 (19.07)	74.08 (17.91)	72.06 (17.68)	71.14 (17.97)
Post-intervention	82.82 (21.37)	83.76 (18.95)	75.84 (20.28)	74.70 (20.23)
NGSE				
Baseline	26.19 (7.57)	25.71 (8.35)	26.19 (7.57)	25.71 (8.35)
Mid-intervention	29.14 (7.30)	28.26 (6.31)	28.37 (7.47)	27.66 (6.94)
Post-intervention	31.36 (7.82)	32.61 (4.78)	29.39 (8.22)	29.35 (7.16)
SCCS				
Baseline	31.59 (10.85)	32.95 (10.72)	31.59 (10.85)	32.95 (10.72)
Mid-intervention	34.40 (10.56)	34.01 (10.61)	33.23 (11.00)	33.46 (10.49)
Post-intervention	39.28 (12.26)	42.28 (11.10)	35.46 (12.12)	36.67 (11.79)
RSES				
Baseline	23.41 (5.31)	23.41 (5.56)	23.41 (5.31)	23.41 (5.56)
Mid-intervention	26.03 (5.55)	25.47 (5.17)	25.18 (5.57)	24.77 (5.43)
Post-intervention	27.77 (5.57)	29.13 (5.58)	25.84 (6.08)	26.21 (6.27)
SCS				
Baseline	62.12 (15.77)	60.86 (17.52)	62.12 (15.77)	60.86 (17.52)
Mid-intervention	71.67 (19.31)	70.54 (16.95)	69.18 (18.78)	67.74 (17.52)
Post-intervention	80.21 (22.43)	82.01 (20.69)	73.32 (21.40)	71.97 (21.31)

We will exemplify below, through the graphs of several outcomes, the way in which the clinical symptoms decreased, respectively the levels of the self-concepts improved, for all the participants.

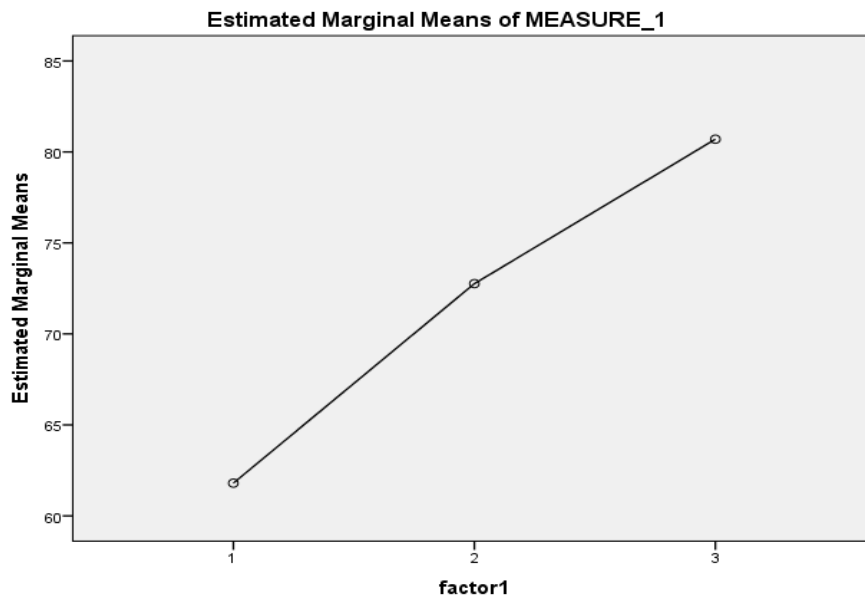
For Generalized Anxiety Disorder



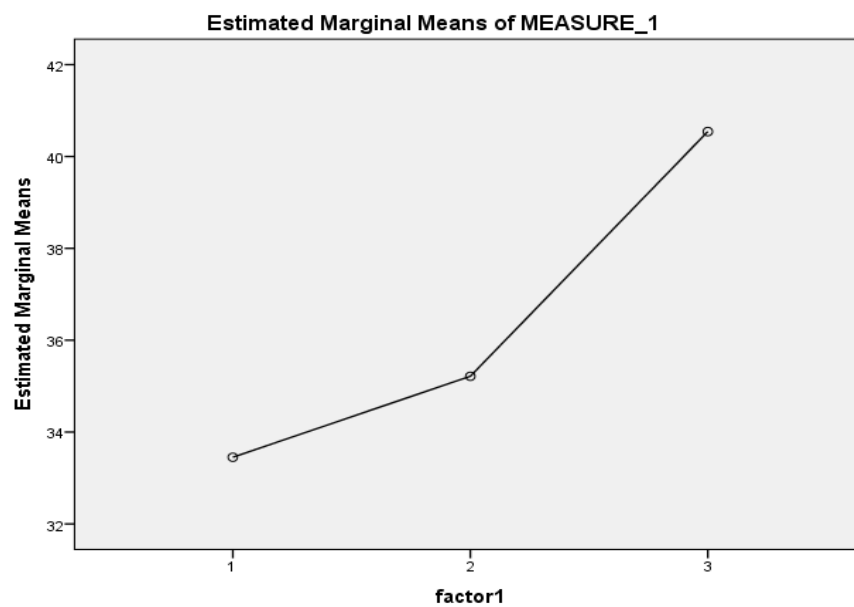
For Beck Depression Inventory-II



For Self-Compassion Scale



For Self-Concept Clarity Scale



According to ANOVA tests, we have statistically significant values within each treatment group, for each category of symptoms separately, measured with different instruments. It can be seen how the symptoms decreased from pretest, to midtest and to posttest for each clinical and nonclinical condition.

In the case of the self-concept dimensions, we also have statistically significant values within each treatment group, it can be seen how all five measured dimensions increased in value: unconditional self-acceptance, self-compassion, self-esteem, self-concept clarity and self-efficacy.

On the other hand, the values of the ANOVA tests are statistically insignificant when we talk about the comparison between the two intervention groups. There are no differences between the two types of interventions applied in the therapeutic program.

Regarding the size of the effect, inside each group it is observed how the effect is greater in the case of the participants who carried the program to the end, than in the case of those who gave up along the way. In the situation of comparing the two intervention groups, the value of the effect size is not significant.

Table 3

The effect size inside each treatment group and between the two groups

Outcome	Model	Within		Within-group Cohen's d (95% CI) SELF	Within-group Cohen's d (95% CI) PsiTad	Within X Intervention type		Between-group Cohen's d (95% CI)
		F (df)	P			F (df)	P	
PHQ9	Completers	126.44 (1, 146)	< .001	1.04 (.73, 1.34)	1.28 (.97, 1.58)	0.068 (1, 146)	.795	-.19 (-.51, .13)
	Intent to treat	90.63 (1, 275)	< .001	.49 (.33, .64)	.43 (.31, .56)	0.016 (1, 275)	.899	.03 (-.21, .26)
SPIN	Completers	88.42 (1, 148)	< .001	.56 (.32, .81)	.83 (.64, 1.03)	1.622 (1, 148)	.205	-.31 (-.63, .01)
	Intent to treat	69.50 (1, 276)	< .001	.33 (.20, .46)	.41 (.29, .52)	1.275 (1, 276)	.260	-.11 (-.12, .35)
PSWQ	Completers	133.12 (1, 147)	< .001	.75 (.49, 1.01)	1.09 (.83, 1.36)	1.889 (1, 147)	.171	-.32 (-.64, .01)
	Intent to treat	94.10 (1, 275)	< .001	.43 (.29, .58)	.52 (.38, .66)	1.405 (1, 275)	.237	-.12 (-.12, .35)
BDI-II	Completers	223.58 (1, 150)	< .001	1.34 (1.00, 1.69)	1.47 (1.17, 1.76)	0.243 (1, 150)	.622	-.14 (-.45, .18)
	Intent to treat	134.00 (1, 277)	< .001	.56 (.41, .71)	.57 (.44, .71)	0.179 (1, 277)	.672	-.04 (-.20, .27)
BDI-II suicide	Completers	21.03 (1, 150)	< .001	.36 (.11, .61)	.49 (.30, .69)	0.025 (1, 150)	.875	-.18 (-.49, .14)
	Intent to treat	19.89 (1, 277)	< .001	.20 (.05, .34)	.19 (.10, .29)	0.029 (1, 277)	.865	-.03 (-.21, .26)
WSAS	Completers	89.29 (1, 142)	< .001	.86 (.52, 1.19)	.98 (.72, 1.24)	0.071 (1, 142)	.790	-.13 (-.45, .20)
	Intent to treat	68.93 (1, 279)	< .001	.45 (.28, .61)	.38 (.26, .49)	0.190 (1, 279)	.664	.05 (-.18, .29)

Table 3 (continued)

Outcome	Model	Within		Within-group Cohen's d (95% CI) SELF	Within-group Cohen's d (95% CI) PsiTad	Within X Intervention type		Between-group Cohen's d (95% CI)
		<i>F</i> (<i>df</i>)	<i>P</i>			<i>F</i> (<i>df</i>)	<i>P</i>	
PDSS	Completers	46.55 (1, 145)	< .001	.38 (.17, .59)	.68 (.46, .89)	1.599 (1, 145)	.208	-.35 (-.67, -.03)
	Intent to treat	40.66 (1, 274)	< .001	.21 (.10, .32)	.29 (.18, .39)	1.498 (1, 274)	.222	-.15 (-.08, .39)
ASI	Completers	82.37 (1, 142)	< .001	.44 (.27, .61)	.79 (.57, 1.01)	0.004 (1, 142)	.952	-.37 (-.69, -.04)
	Intent to treat	64.62 (1, 280)	< .001	.30 (.20, .40)	.29 (.19, .40)	0.029 (1, 280)	.865	.02 (-.21, .25)
GAD	Completers	107.74 (1, 144)	< .001	.92 (.63, 1.21)	1.28 (.93, 1.63)	1.086 (1, 144)	.299	-.25 (-.57, .07)
	Intent to treat	79.83 (1, 274)	< .001	.44 (.29, .58)	.49 (.34, .65)	0.694 (1, 274)	.406	-.08 (-.15, .32)
ATQ	Completers	106.33 (1, 141)	< .001	.75 (.51, 1.00)	1.12 (.86, 1.39)	0.564 (1, 141)	.454	-.32 (-.65, .01)
	Intent to treat	77.85 (1, 279)	< .001	.36 (.23, .48)	.39 (.28, .51)	0.239 (1, 279)	.625	-.06 (-.18, .29)
ODSIS	Completers	52.08 (2, 139)	< .001	.82 (.57, 1.08)	.90 (.67, 1.13)	0.017 (2, 139)	.983	-.12 (-.44, .21)
	Intent to treat	44.35 (2, 279)	< .001	.44 (.30, .58)	.39 (.27, .52)	0.065 (2, 279)	.937	.04 (-.20, .27)
OASIS	Completers	68.07 (2, 140)	< .001	.91 (.63, 1.20)	.97 (.72, 1.22)	1.071 (2, 140)	.346	-.10 (-.42, .23)
	Intent to treat	54.16 (2, 279)	< .001	.57 (.41, .72)	.50 (.35, .65)	1.542 (2, 279)	.216	-.04 (-.19, .28)
USAQ	Completers	48.59 (2, 137)	< .001	.78 (.57, .99)	.90 (.67, 1.13)	0.105 (2, 137)	.901	-.07 (-.40, .25)
	Intent to treat	46.88 (2, 276)	< .001	.44 (.31, .57)	.39 (.27, .51)	0.146 (2, 276)	.864	.07 (-.17, .30)
NGSE	Completers	41.81 (2, 137)	< .001	.67 (.44, .91)	.96 (.67, 1.25)	1.929 (2, 137)	.149	-.23 (-.55, .10)
	Intent to treat	39.78 (2, 273)	< .001	.40 (.27, .54)	.46 (.32, .61)	1.197 (2, 273)	.304	-.07 (-.17, .31)
SCCS	Completers	44.37 (2, 138)	< .001	.66 (.41, .91)	.85 (.63, 1.08)	1.603 (2, 138)	.205	-.16 (-.48, .16)
	Intent to treat	33.08 (2, 273)	< .001	.33 (.19, .48)	.33 (.20, .46)	0.918 (2, 273)	.401	.02 (-.22, .25)
RSES	Completers	60.544 (2, 138)	< .001	.80 (.55, 1.05)	1.03 (.78, 1.28)	4.519 (2, 138)	.013	-.27 (-.59, .06)
	Intent to treat	51.40 (2, 279)	< .001	.42 (.29, .55)	.47 (.34, .60)	3.249 (2, 279)	.040	-.09 (-.15, .32)
SCS	Completers	54.83 (2, 139)	< .001	.92 (.61, 1.23)	1.10 (.78, 1.41)	0.154 (2, 139)	.857	-.21 (-.53, .12)
	Intent to treat	49.85 (2, 273)	< .001	.58 (.40, .76)	.56 (.40, .72)	0.028 (2, 273)	.972	.00 (-.23, .24)

There are also no significant differences between groups, either in terms of the number of solved modules or in terms of the credibility of the treatment. The questions were the following:

1. How logical do you think it is a method of delivering a treatment on the internet?
2. How confident are you that the program will help you to manage better your emotions?
3. Would you recommend this program to a friend with the same emotional difficulties?
4. How effective is this program in managing other uncomfortable emotions?
5. How confident are you that you will make improvements at the end of this program?

Also, in the final part, the participants were asked about the level of satisfaction with the treatment they received. The questions were the following:

1. Overall, how satisfied are you with the treatment you received?
2. How would you evaluate the quality of the information that were provided?
3. How satisfied were you with the timing of the treatment program?
4. How many modules did you fully understand?
5. Please, estimate the average number of hours you spent in a week in the program.
6. How demanding were the activities?
7. The program helped me approach my problems more effectively.
8. How logical seemed to you the method that we used?
9. How confident would you be to recommend this method of treatment?

The values of the independent *t* tests for the answers of the participants from the two intervention groups, to the questions of the questionnaire regarding the level of the satisfaction with the treatment they received, are statistically insignificant.

Table 4

Level of participants' satisfaction with the received treatment

Outcome	Treatment (Self) M (SD)	Control (PsiTad) M (SD)
Number of completed modules	5.97 (3.08)	5.60 (3.17)
How logical do you think it is a method of delivering a treatment on the internet?	8.18 (1.78)	8.22 (1.85)
How confident are you that the program will help you to manage better your emotions?	7.45 (2.02)	7.66 (1.89)
Would you recommend this program to a friend with the same emotional difficulties?	8.16 (1.82)	8.21 (1.89)

Table 4 (continued)

Outcome	Treatment (Self) M (SD)	Control (PsiTad) M (SD)
How effective is this program in managing other uncomfortable emotions?	7.31 (1.92)	7.35 (1.86)
How confident are you that you will make improvements at the end of this program?	7.81 (1.71)	7.74 (1.77)
Overall, how satisfied are you with the treatment you received?	4.35 (.75)	4.40 (.70)
How would you evaluate the quality of the information that were provided?	4.60 (.92)	4.52 (.97)
How satisfied were you with the timing of the treatment program?	2.54 (.83)	2.58 (.84)
How many modules did you fully understand?	7.01 (1.88)	7.16 (1.88)
Please, estimate the average number of hours you spent in a week in the program.	4.79 (4.29)	4.95 (4.98)
How demanding were the activities?	2.78 (.65)	2.77 (.75)
The program helped me approach my problems more effectively.	3.47 (.55)	3.38 (.63)
How logical seemed to you the method that we used?	8.25 (1.89)	8.08 (2.07)
How confident would you be to recommend this method of treatment?	8.52 (1.77)	7.94 (2.67)

After 6 months from the end of the treatment program, we performed the follow-up measurements. As it can be seen below, there are no statistically significant differences between the two treatment groups for any measurement.

Table 5

Follow-up measurements

Group Descriptives					
	Group	N	Mean	SD	SE
SCStotal_F	PsiTAD	35	83.486	20.932	3.538
	SELF	31	82.935	24.802	4.455
RSEStotal_F	PsiTAD	34	29.441	5.986	1.027
	SELF	29	29.103	6.951	1.291
SCCStotal_F	PsiTAD	36	44.500	8.856	1.476
	SELF	33	44.182	11.796	2.053
NGSEtotal_F	PsiTAD	35	31.457	6.792	1.148
	SELF	32	32.656	6.646	1.175

Table 5 (continued)

Group Descriptives					
	Group	N	Mean	SD	SE
PHQ9total_F	PsiTAD	37	5.568	5.036	0.828
	SELF	33	5.697	5.955	1.037
GAD7total_F	PsiTAD	36	5.500	5.273	0.879
	SELF	33	5.212	5.171	0.900
ATQtotal_F	PsiTAD	34	31.118	13.595	2.332
	SELF	30	31.233	16.156	2.950
USAQ_Total_F	PsiTAD	34	86.853	19.176	3.289
	SELF	29	83.138	19.915	3.698
ASItotal_F	PsiTAD	34	16.176	13.442	2.305
	SELF	29	19.828	15.031	2.791
PDSSTotal_F	PsiTAD	38	2.105	3.593	0.583
	SELF	33	2.000	3.437	0.598
WSAStotal_F	PsiTAD	34	7.441	8.027	1.377
	SELF	30	8.867	8.625	1.575
BDIITotal_F	PsiTAD	43	8.721	9.437	1.439
	SELF	36	9.194	9.374	1.562
BDIISuicid_F	PsiTAD	43	0.093	0.294	0.045
	SELF	36	0.111	0.523	0.087
PSWQTotal_F	PsiTAD	40	49.525	10.551	1.668
	SELF	36	53.056	12.737	2.123
SPINTOTAL_F	PsiTAD	39	20.077	13.857	2.219
	SELF	35	22.057	15.518	2.623
ODSISTotal_F	PsiTAD	35	3.171	4.211	0.712
	SELF	29	2.586	3.905	0.725
OASISTotal_F	PsiTAD	35	3.629	3.797	0.642
	SELF	30	3.133	3.401	0.621

These results show that whether you perform a specific therapeutic intervention dedicated to the self-concepts or simply perform a classic intervention for clinical emotional problems, the self-parameters will modify in order to increase their level.

Table 6

The effect size at follow-up measurements

Independent Samples T-Test				
	t	df	p	Cohen's d
SCStotal_F	0.098	64.000	0.922	0.024
RSEStotal_F	0.207	61.000	0.837	0.052
SCCStotal_F	0.127	67.000	0.899	0.031
NGSEtotal_F	-0.729	65.000	0.468	-0.178
PHQ9total_F	-0.098	68.000	0.922	-0.024
GAD7total_F	0.229	67.000	0.820	0.055
ATQtotal_F	-0.031	62.000	0.975	-0.008
USAQ_Total_F	0.753	61.000	0.454	0.190
ASItotal_F	-1.018	61.000	0.313	-0.257
PDSSTotal_F	0.126	69.000	0.900	0.030
WSAStotal_F	-0.685	62.000	0.496	-0.171
BDIITotal_F	-0.223	77.000	0.824	-0.050
BDIISuicid_F	-0.194	77.000	0.847	-0.044
PSWQTotal_F	-1.321	74.000	0.191	-0.303
SPINTOTAL_F	-0.580	72.000	0.564	-0.135
ODSISTotal_F	0.572	62.000	0.570	0.144
OASISTotal_F	0.550	63.000	0.584	0.137
<i>Note.</i> Student's t-test.				

5. CONCLUSIONS

This study has a non-inferiority design because we started from the idea that we have two types of interventions that have a common segment: the therapeutic program for clinical anxiety and depression. We added some techniques to one of the interventions to produce changes at the level of self-concepts: self-compassion, unconditional self-acceptance, self-esteem, self-concept clarity, self-efficacy.

At the end of the study, there were no statistically significant differences between the two intervention groups for any of the 17 measurements; neither post-test nor follow-up. All statistically significant differences existed only within each treatment group, showing the progress made by all participants throughout the therapeutic program. The beneficial effects on their mental state, the decrease of the symptoms from anxiety and depression and the raising of the self parameters were preserved even at 6 months after the end of the interventions, for both groups.

The major final conclusion of this study is that whether or not, in an intervention dedicated to reduce the symptoms of anxiety and depression, we perform a specific intervention to increase the level of some self-concepts, the

latter will modify anyway in an ascending direction. This happens because after any correctly implemented psychological intervention, the patients will adapt to new life situations helped by the process they went through and there happened beneficial changes in themselves, precisely to facilitate this process of inner healing and adaptive functioning in the outside world.

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REZUMAT

Context și obiective: În ultimii ani, programele terapeutice livrate online au început să se dezvolte din ce în ce mai mult. Cu toate acestea, nu există multe studii clinice care să compare eficacitatea a două intervenții clinice, ambele furnizate online. Scopul principal al acestui studiu a fost de a investiga eficacitatea și acceptabilitatea unei intervenții transdiagnostice online, vizând simptomele clinice ușoare până la moderate de anxietate și depresie și subliniind schimbările care au loc la nivelul structurilor sinelui. Scopul secundar a fost de a compara această intervenție cu o intervenție transdiagnostic standard în anxietate și depresie, într-un studiu randomizat de noninferioritate.

Metodă: Un total de 284 de participanți au fost repartizați aleatoriu într-una dintre cele două intervenții. Eficacitatea unui tratament cognitiv-comportamental transdiagnostic a fost comparată cu o altă versiune a acestuia, în care s-au adăugat noi tehnici de intervenție, subliniind importanța îmbunătățirii unor dimensiuni ale conceptului de sine, în reducerea simptomelor de anxietate și depresie. Pentru a demonstra acest lucru, designul studiului a inclus două grupuri de intervenție activă.

Un protocol standard de intervenție transdiagnostic a fost livrat unui grup ($n=141$) și o versiune îmbunătățită a aceluiași protocol transdiagnostic a fost aplicat celuilalt grup ($n=143$). Noile tehnici adăugate au vizat unele concepte ale sinelui: autocompasiunea, acceptarea necondiționată de sine și stima de sine. Prin urmare, scopul principal al studiului a fost de a testa simultan eficacitatea acestor două abordări transdiagnostice, în reducerea simptomelor de anxietate și depresie și îmbunătățirea conceptelor de sine menționate mai sus.

Rezultate: Atât analiza celor care au început tratamentul, dar s-au oprit pe parcurs, cât și cea a celor care au finalizat tratamentul nu au dat nicio diferență semnificativă între grupuri, pentru niciuna dintre măsurătorile postintervenției. La posttratament, ambele condiții de intervenție au evidențiat modificări semnificative ale simptomelor, în comparație cu situația de dinainte de intervenție. Mărimile efectului în interiorul grupului, pentru scăderea anxietății (GAD7), au fost: într-un grup de intervenție ($d=0,92$) și în celălalt grup de intervenție ($d=1,28$) și pot fi considerate ridicate. Mărimile efectului în interiorul grupului, pentru scăderea depresiei (BDI-II), au fost: într-un grup de intervenție ($d=1,34$) și în celălalt grup de intervenție ($d=1,47$) și pot fi, de asemenea, considerate ridicate. La 6 luni de la tratament, rezultatele au rămas stabile în ambele grupuri de intervenție.

Concluzii: Nu am găsit diferențe semnificative statistice între cele două grupuri de intervenție, nici la măsurătorile de la posttest, nici la cele de *follow-up*, astfel încât creșterea nivelului conceptelor de sine apare în ambele situații, indiferent dacă facem o intervenție directă în acest sens sau dacă realizăm o intervenție clasică în anxietatea și depresia clinică.