Iconic therapy for the reduction of borderline personality disorder symptoms among suicidal youth: A randomized controlled trial study

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Iconic therapy for the reduction of borderline personality disorder symptoms among suicidal youth: A randomized controlled trial study

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Abstract

Background: Iconic therapy (IT) is a new therapy that uses images to teach skills with the aim of improving the symptoms of borderline personality disorder. Preliminary results are promising and the indication is that Iconic Therapy may be effective. The purpose of this randomized clinical trial was to test the effectiveness of IT compared to a psychological supportive intervention (SI).

Methods: The study was carried out at the University Regional Hospital of Malaga. Young patients (N=40; 15–30 years) with suicidal or parasuicidal behavior and borderline personality traits were randomized into IT (N = 20) or SI (N = 20). The main outcome variable was a change in the symptoms of borderline personality disorder (BSL-23) at the end of treatment. The secondary outcome variables were suicidal ideation and behaviour, self-harm, the need for medication, the number of visits to mental health professionals, maladaptive behaviour, satisfaction with therapy and perceived improvement, both at the end of the intensive treatment and at the 12-month follow-up.

Results: There were no significant differences between the two therapies regarding reduction of the BSL-23 score. The two therapies showed statistically significant results both at the end of intensive treatment (IT: $d = 0.50$; SI: $d = 0.45$) and at the 12-month follow-up (IT: $d = 1.09$; SI: $d = 0.80$). In the secondary outcome measures, IT showed statistically significant superiority with respect to SI in satisfaction with therapy at the end of treatment ($p = 0.002$).

Conclusions: Although the results suggest certain superiority of Iconic therapy, it is remarkable the necessity of future studies with larger samples and comparisons with established treatments for borderline personality disorder.

Clinical Trial Registration: ClinicalTrials.gov identifier: NCT03011190.

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Keywords: iconic therapy; borderline personality disorder; psychological therapy; suicide; clinical trial.

1 Background

Borderline personality disorder (BPD) is characterized by a pattern of instability in the regulation of emotions, self-image, behaviour control and interpersonal relationships (1). BPD is especially prevalent in young individuals, with a peak prevalence in early adulthood (2). In young populations the symptoms of BPD are associated with an increased risk of suicide (3). Suicidal ideation usually moves adolescents to seek for professional help (4). Preventive psychological treatment in the early stages of the disease may be the best long-term strategy, as new studies indicate high flexibility in BPD traits at this stage and adequate response rates to the treatments studied (5,6). However, suicidal attempts are particularly difficult to keep under control through psychotherapy in adolescents according to a recent metanalysis (7).

Among the evidence-based treatments for BPD according to clinical practice guidelines are psychological treatments (8). Those psychological treatments showing more evidence of effectiveness are dialectic behavioural therapy, mentalization-based therapy and transference-focused therapy (9). These therapies are very intensive and require the use of many therapeutic sessions for long periods of time, what is often a major impediment for unstable patients to complete the treatment. In addition, most of the evidence on these therapies comes from studies conducted at centres of excellence, so their generalizability is not well established (8). However, there is no evidence of the superiority of prolonged treatments compared to brief treatments for BPD (10,11).

On the other hand, recent research shows that BPD is associated with cognitive deficits in executive function (12) and attention (13). These alterations can hinder the brief traditional psychotherapeutic approach and therefore, any kind of extra support to increase their effectiveness may be helpful. Visual aids could be an alternative, as images can improve learning (14) and also promote the creation of positive mental representations, which have been shown to have a causal role in mood and can even improve depressive symptoms (15).

Iconic therapy (IT) is an integrative therapy that uses images to teach attitudes and skills for improving the symptoms of BPD. Its major aportation is a brief, highly structured program to help those affected by BPD acknowledge their emotions and improve the ability to function. The program includes both an explicative model of unstable behaviors and a therapeutic model. The explicative model addresses the origins and mechanisms of perpetuation of unstable relationships, moods, thinking and behaviors so that BPD patients feel validated and increase their cognitive insight. The therapeutic model orders and adapts interventional principles of existing current treatments to increase the chances of therapeutic success. These models, interconnected with arrows in a flowchart, help patients head from unstable behaviors to more adaptive ones in a kind of “visual step by step map”. Simultaneously, Iconic Therapy works on BPD vulnerability factors (dichotomy, rumination, low self-esteem, wrong beliefs, external control locus or codependence). Iconic Therapy’s denomination is due to the symbolic representation of given therapeutic principles (acceptance, problem solving, resilience, self-direction or empathy) in a total of 35 images (icons). Images include generic objects of our environment (such as a table, a sailboat or a tower of books) whose emotional valence is neutral. These icons, together with the flowchart (or map) of the program, simplify the

100 explanation of a wide variety of complex social situations, usually inaccessible for BPD
101 patients. In summary, Iconic Therapy provides a much-needed full paronamic vision of
102 BPD that brings awareness (insight) and intention (control) for affected patients to cope
103 with everyday tasks. Iconic Therapy's good acceptance among adolescents may be
104 precisely related to their natural use of images and metaphors in daily life. Guidelines for
105 Iconic Therapy have been prepared and are currently pending publication. It contains
106 examples and a number of therapists' considerations that may easily be translated and
107 exported to many other languages and cultures. The program is divided into four modules,
108 focusing on basic coping skills, interpersonal relationships, self-esteem and identity and,
109 finally, self-direction. In clinical practice this therapy has been developed as an initial
110 intensive 10–12-week phase of weekly group sessions and variable individual sessions.
111 The second phase of treatment consists of a 12-month follow-up with individual support
112 sessions. Some preliminary studies have shown promising results but with the limitation
113 of small samples (16,17). So far, no controlled clinical trial of IT has been carried out.

114 The objective of the study was to analyse the effectiveness of IT for reducing
115 symptomatology in young individuals with BPD traits and suicidal behaviour in
116 comparison with psychological supportive intervention (SI). The primary outcome of the
117 study is a decrease in severity of the BPD symptoms at the end of the intensive treatment.

118 **2 Methods and Materials**

119 **2.1 Procedure**

120
121 The study was a two-armed parallel randomized controlled trial (RCT). The
122 Provincial Ethics and Research Committee of Malaga approved and registered the study
123 (shs-ico-2015-01). Informed consent to participate was obtained from all participants
124 and parental consent was obtained for participants under the age of 18 years. The
125 sample size calculation was based on our primary outcome measure, BPD symptom
126 severity at 12 months. A sample size of 26 participants per group was required to detect
127 a post-treatment effect size of 0.20 (Cohen's d) between both groups with a power of
128 0.80 in a one-tailed test, and with a 95% confidence level. The total sample size was
129 then determined at 52 participants, but only 40 individuals could finally be recruited.
130 More details about the trial have been published previously in the study protocol (18).
131 In short, the study was conducted at the University Regional Hospital of Malaga during
132 January 2016 and July 2017. Patients were informed of the study by psychologists and
133 psychiatrists working in the public community care system and if they were interested
134 in participating a study researcher was notified. If the participants met the inclusion
135 criteria, they were randomized in a 1:1 ratio by the principal investigator into two
136 interventions: IT or SI (which does not use images during the therapeutic process). In
137 the two comparison groups, participants followed their usual treatment within the public
138 health system. All the therapists were volunteers with a master's degree in psychology.
139 Four therapist and four co-therapists administered the two therapy groups, forming a
140 total of four groups (two for each intervention). It was inherently not possible to blind
141 psychologists delivering the Iconic Therapy intervention since they had been
142 specifically trained for 10 months. The goal of the psychologists conducting the control
143 group was to obtain good clinical results through therapeutic intervention. Also, two
144 group sessions were recorded to assess the fidelity of the therapy. Supervision and
145 feedback were given to the therapist and co-therapist by the principal investigator
146 during the study for both therapy groups. It was considered that the participants had
147 completed treatment if they attended at least 80% of the sessions.

This study was approved by the Ethics and Research Committee of the Regional University Hospital of Málaga. The study design and performance complied with the Declaration of Helsinki.

2.2 Participants

The sample of this study was composed of 40 participants: $N = 20$ in the Iconic Therapy group, and $N = 20$ in the control group. The inclusion criteria were: 15–30 years old, presence of suicidal ideation (two or more questions about suicidal ideation affirmatively reported in the Columbia Suicide History Form), borderline personality symptoms (score of ≥ 38 out of 84 on the Exploratory Questionnaire of Personality-III-BPD) and sufficiently proficient in Spanish to conduct the treatment. The exclusion criteria were antisocial personality disorder, substance/alcohol abuse or dependence, and not enough motivation to participate in treatment (score of ≥ 35 out of 60 points on the Credibility/Expectancy Questionnaire). Recruitment lasted 2 months (November and December'15). Clinical interventions took place between January and June'16. The study ended in July'17. Sociodemographic characteristics of the participants are shown in Table 1.

2.3 Instruments

The primary outcome measure was the severity of BPD assessed with the *Borderline Symptom List* (BSL-23) (19). The secondary outcome measures were: suicidal ideation with the *Columbia-Suicide Severity Rating Scale*; (20) suicide attempts; non-suicidal self-injury assessed following the criteria from DSM-V (21) (suicide attempts and non-suicidal self-injury were evaluated for 12 months before baseline, during treatment and at follow-up); and maladjustment to daily life with the *Maladjustment Scale* (22). Because of the underpowered sample size to conduct economic analysis, it was decided not to use the *Client Service Receipt Inventory* (23) in the study protocol and only collect information on the medication and visits to mental health professionals. After the treatment was evaluated, satisfaction with treatment was assessed with an adaptation of the *Credibility/Expectancy Questionnaire* (24) and perceived global improvement from participants and family/friends (seven-point Likert scale). The following sociodemographic variables were assessed at baseline: gender, age, marital status, parent's nationality, cohabitation, educational level and occupational status.

2.4 Interventions

2.4.1 Iconic therapy

Therapy consisted of a 10-session programme structured into four modules: motivation and coping skills; intimacy/empathy; identity; and self-direction. Each module has two or three weekly group sessions of 90 min duration. In the first 30 min, practical use of the last session's icons is discussed and then new icons are presented. In the second part of the programme supportive individual face-to-face sessions were conducted by the principal investigator. Additionally, three more group sessions were conducted after treatment and at 6- and 12-month follow-ups. The objective of these sessions was to minimize drop-outs and try to meet the specific needs of the participants. A therapist and co-therapist conducted the group. The IT programme was delivered by therapists trained in IT specifically for this study and group sessions were supervised from behind a unidirectional window by the principal investigator. The four therapists who delivered this therapy followed 10 months of training (10 sessions).

2.4.2 Psychological supportive intervention

This SI treatment consisted of a 10-session programme of 60 min per week. The sessions were 30 min shorter than the IT sessions because the verbal nature of the intervention does not require as much practical clarification by the therapists and long sessions could affect adherence. This therapy had a psychoeducational nature, with modules focused on the improvement of social relationships and skills, assertiveness, self-esteem, impulse control and learning relaxation techniques and mindfulness. As in IT, the second part of the programme consisted of three group sessions and a variable number of individual face-to-face sessions conducted by the principal investigator. More information about the content of both IT and SI is given in the previously published protocol (18).

2.5 Statistical analysis

An intention-to-treat analysis was carried out on all the participants, irrespective of whether they were completers. Demographic characteristics were summarized with descriptive statistics and differences between treatment groups were examined using the chi square test for categorical variables and *t*-tests for continuous variables if normality was fulfilled (if not, the Mann-Whitney U test was used). Also, for suicide attempts and non-suicidal self-injury, McNemar's test was conducted to analyse the change between the previous year of baseline and at follow-up for these variables.

Analyses for primary and secondary outcomes were carried out using generalized estimating equation (GEE) models. In brief, GEE models are an extension of generalized linear models for repeated measures or correlated observations. In addition, GEE models can also deal with data that have missing values, as long as the missing value is completely random. This means that analyses are computed with all participants (in this study, $N = 40$), even if some of them have a missing value. Parameter estimation can still yield robust results.

Intervention conditions (IT vs. SI) will be included for the between-subjects factor and time (baseline, after treatment and at 12-month follow-up) as the repeated measure. Main effects and interaction between treatment and time were analysed. A sensitivity analysis was carried out with the different correlation matrices (independent, AR (1), interchangeable, M-dependent and unstructured) and the model with the lower QIC was selected. IBM SPSS (Version 22.0 for Windows) software was used and statistical significance was considered at $p < .05$. Bonferroni correction was applied for post hoc multiple comparisons.

3 Results

As shown in Table 1, there were no significant differences in the sociodemographic variables between the two groups at baseline. The information about recruitment is shown in a flow-chart diagram in Figure 1. IT showed a higher adherence compared to SI (70% vs. 45%), although the differences were not statistically significant ($p = 0.110$), and also a lower drop-out rate at the last follow-up (15% vs. 25%), although these differences also were not significant ($p = 0.429$). More information is shown in Table 1. The average values and frequency of the outcome variables in the three assessments appear in Table 2.

For the primary outcome there were no significant differences between the two therapies at the end of treatment (difference in means for IT vs. SI: -11.30 vs. -8.52 ; $p = 0.812$; Cohen's $d = 0.123$) and at the 12-month follow-up (difference in means for IT vs. SI: -21.88 vs. -14.33 ; $p = 0.309$; Cohen's $d = 0.321$). The results for the primary outcome in the three time periods can be seen in Figure 2.

There were no significant differences between the two interventions when all measures were included in the analysis, as the interaction between the therapy and the assessment at the end of the treatment and the follow-up were not significant for any of the outcome measures (see Table 3). Both therapies showed significant reductions at post-treatment and follow-up in the symptoms of BPD, suicidal ideation and functionality in daily activities.

Regarding other secondary outcomes, there were only significant differences in satisfaction with therapy at the end of treatment, with better results for IT (43.40 vs. 34.26; $p = 0.002$) that maintain significance after Bonferroni correction for multiple comparisons ($p = 0.040$). At the 12-month follow-up, the difference was not significant for satisfaction between IT and SI (47.88 vs. 44.13; $p = 0.354$). There were fewer suicide attempts in the IT group until the end of treatment (25.00% vs. 47.36%), although the differences did not reach statistical significance ($p = 0.533$). Analyses on all outcome variables are shown in Table 4.

4 Discussion

This clinical trial has shown that IT is feasible for applying in a real clinical environment with therapists taught IT for the first time and it was associated with greater satisfaction at the end of treatment than a SI. IT showed a trend to better adherence than SI, although the differences only approached statistical significance. The differences were not significant for the main outcome and both therapies showed significant reduction in borderline symptoms.

The results show that after IT and after a supportive therapy the symptoms of BPD were reduced and the magnitude was comparable to those found by other well-established psychotherapies using the BSL-23 as primary outcome (25). In addition, IT was associated with higher satisfaction compared to non-specific SI. These results are partially in line with studies showing that specific group therapies give better results (26) for patients with BPD traits, although it is necessary to carry out more extensive trials with IT to assess its specificity.

Several RCTs have not shown significant differences when comparing two different psychological interventions in BPD (27–30), whereas others have shown differences but the majority of these used small samples or have a high risk of bias (31,32). Generally, evidence on the differential effectiveness of psychological interventions is very poor and more studies are needed to determine which factors are responsible for the improvement of outcomes.

Regarding applicability and implementation in the real world, the results would be aligned with the results of other studies indicating an alternative staggered treatment for BPD (11), because the accessibility of long treatments such as behavioural dialectic therapy or mentalization-based treatment is limited due to the large amount of resources needed and the lack of experienced therapists. This type of short therapy would adapt especially well to a young population with acute symptoms (33). Furthermore, in certain patients, mainly in the early stages of the disorder, long-term treatment may not be necessary, as several studies suggest (25,34–36). These results are linked to the body of evidence suggesting that structured preventive strategies in the early stages of the disorder may be an adequate alternative (37).

One of the main limitations of the study is that the sample size was not of the required size due to unexpected difficulties in the recruitment process, thus the sample was small and underpowered for detecting small effect sizes. A second limitation is that, due to recruitment problems, the inclusion and exclusion criteria needed to be modified

by extending the age range and by not using an instrument that was in the study protocol. Finally, structured questionnaires were used for the selection of participants, not structured clinical interviews, however the questionnaires show adequate psychometric properties. Despite these limitations, the trial shows some strengths, such as the low percentage of drop-outs in the follow-up (20%) and the large percentage of participants who completed at least 80% of the sessions (57.5%). Another strength is that the trial was conducted in a real world scenario where clinical staff were included along with non-experienced therapists, thus the study had high external validity.

5 Conclusions

There were no significant differences between IT and SI for the primary outcome, however IT was significantly associated with greater satisfaction at the end of treatment. Future studies are needed to verify the effectiveness of IT compared to established therapies for the treatment of BPD and with treatment as usual.

6 Abbreviations

APA: American Psychology Association; BPD: Borderline personality disorder; BSL-23: Borderline Personality Disorder List; CEPER-III-BPD: Exploratory Questionnaire of Personality-III-BPD; CEQ: Satisfaction with therapy; C-SSRS: Columbia Suicide History Form; DBT: Dialectical Behaviour Therapy; DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; GEE: Generalized estimating equations; GLM: Generalized linear models; IG: Maladjustment Scale; MBT: Mentalization-based Therapy; NICE: National Institute for Health and Care Excellence; SCID-II: Clinical Interview for DSM-IV Axis II Disorders; SFT: Schema-focused Cognitive Therapy; STEPPS: Systems Training for Emotional Predictability and Problem Solving; TAU: Treatment as usual; TFP: Transference-focused Therapy;

7 Declarations

Ethics statement

The Provincial Ethics and Research Committee of Málaga has approved this study (reference number shs-ico-2015-01). Informed consent to participate was obtained from all participants prior to inclusion in the study. Also, parental informed consent was obtained for participants under the age of 18.

Availability of data and materials

The datasets used during the current study will be available under reasonable request to the corresponding author.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Funding

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Consent for publication

Not applicable

Author's Contributions

SH made the guideline for Iconic Therapy. All authors contributed in designing and developing the study protocol. SH coordinates the implementation of the study, recruitment of patients and data collection and JGP collaborate in the implementation. RMB developed the statistical design and randomization procedure and RMB and JGP carried out the statistical analyses. SH and JGP wrote the first draft of the manuscript. FM and RMB critically revised the manuscript and approved the final version. All authors read and approved the final manuscript.

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511 **Table 1.** Sociodemographic characteristics of the randomized sample at baseline and
512 attrition to treatment.
513

<i>Variable</i>	Total N=40		Support Therapy N=20		Iconic Therapy N=20		χ^2 / t	<i>p</i>
Age (15-29), M (SD)	20.53	(4.32)	19.95	(4.37)	21.10	(4.30)	-0.83	.407
Gender (<i>Female</i>) (%)	33	(82.5)	15	(75.0)	18	(90.0)	1.55	.405 ^a
Civil Status (<i>Single</i>) (%)	40	(100)	20	(100)	20	(100.0)		
Parent's nationality (Both Spanish) (%)	30	(75.5)	14	(70.0)	16	(80.0)	0.53	.465
Cohabitation with family of origin (%)	35	(87.5)	17	(85.0)	18	(90.0)	0.30	.633
Educational level (%)							4.46	.107
<i>Primary</i>	20	(50.0)	11	(55.0)	9	(45.5)		
<i>Secondary</i>	13	(32.5)	8	(40.0)	5	(25.0)		
<i>Universitary</i>	7	(17.5)	1	(5.0)	6	(30.0)		
Laboral Status (%)							0.46	.792
<i>Unemployed</i>	14	(35.0)	6	(30)	8	(40)		

<i>Partial Time Job</i>	4	(10.0)	2	(10)	2	(10)		
<i>Full Time Job</i>	22	(5.5)	12	(60)	10	(50)		
Complete follow-up (%)	32	(80.0)	15	(75)	17	(85)	0.62	.693 ^a
Complete the treatment (<i>Number of group sessions</i> ≥8) (%)	23	(59.0)	9	(45.0)	14	(70.0)	2.56	.110 ^a
Number of individual sessions, M (SD)	3.15	(3.39)	2.21	(2.37)	4.05	(3.99)	-1.73	.091

Table 2. Description of the outcome variables in each therapy group (Structured Therapy or Iconic Therapy).

Variable	Therapy	Baseline		Post- treatment (10 weeks)		Follow-up (12 months)	
		M	(SD)	M	(SD)	M	(SD)
Symptoms BPD (BSL-23)	Support	52.25	(18.71)	42.63	(24.86)	37.13	(20.53)
	Iconic	51.40	(22.03)	40.10	(24.63)	28.06	(21.82)
Suicide Ideation (C-SSRS)	Support	4.00	(0.97)	2.68	(1.66)	1.33	(1.75)
	Iconic	3.55	(1.46)	2.00	(2.00)	1.00	(1.45)
Suicide Attempt (C-SSRS) N (%)	Support			9	(47.36)	2	(13.33)
	Iconic			5	(25.5)	1	(5.88)
Non-Suicidal Self-injury (DSM-5) N (%)	Support				0	1	
	Iconic	3	(15.0)	1	(5.0)	0	0
Psychopharmacology consumption N (%)	Support	14	70.0%	10	52.6%	8	53.3%
	Iconic	14	70.0%	11	55.0%	5	29.4%
Visits to mental health professionals	Support			1.95	(2.99)	4.82	(6.21)
	Iconic			1.85	(2.45)	3.80	(5.71)
Maladjustment to daily life (IG)	Support	23.30	(5.07)	19.21	(9.44)	16.27	(8.68)
	Iconic	20.60	(6.62)	15.10	(7.70)	9.82	(6.69)
Satisfaction with therapy (CEQ)	Support			34.26	(9.92)	44.13	(13.61)
	Iconic			43.40	(6.12)	47.88	(7.52)
Subjective global improvement (Individual)	Support			3.16	(1.01)	2.73	(1.83)
	Iconic			3.10	(1.25)	2.35	(1.17)
Subjective global improvement (Family)	Support			3.42	(0.84)	2.40	(0.99)
	Iconic			3.05	(1.19)	3.12	(1.11)

Table 3. Results of the Generalised Estimated Equations models (GEE).

Outcome variable	B	ES	95% CI	Wald	P
Symptomatology BPD (BSL-23)					
Therapy	0.850	6.302	-11.501/13.201	0.018	.893
Post-Treatment	-11.300	4.279	-19.687/-2.913	6.974	.008
Follow-up	-23.341	6.696	-36.467/-10.215	12.148	.000
Therapy*Post-Treatment	1.682	7.087	-12.208/ 15.572	0.056	.812
Therapy*Follow-up	8.225	8.090	-7.632/24.081	1.033	.309
Suicide ideation (C-SSRS)					
Therapy	0.450	0.384	-0.302/1.202	1.374	.241
Post-Treatment	-1.550	0.364	-2.263/-0.837	18.149	.000
Follow-up	-2.550	0.499	-3.529/-1.571	26.069	.000

Therapy*Post-Treatment	0.234	0.540	-0.824/1.292	0.188	.664
Therapy*Follow-up	-0.117	0.720	-1.527/1.294	0.026	.871
Maladjustment to daily life (IG)					
Therapy	2.700	1.819	-0.864/6.264	2.204	.138
Post-Treatment	-5.500	1.487	-8.415/-2.585	13.672	.000
Follow-up	-10.776	1.819	-14.341/-7.212	35.115	.000
Therapy*Post-Treatment	1.411	2.561	-3.609/6.430	0.303	.582
Therapy*Follow-up	3.743	3.225	-2.578/10.064	1.347	.246
Psychopharmacology consumption					
Therapy	1.009	0.742	-0.446/2.464	1.847	.174
Post-Treatment	-0.714	0.746	-2.176/0.749	0.915	.339
Follow-up	0.028	0.675	-1.296/1.352	0.002	.967
Therapy*Post-Treatment	-0.362	0.960	-2.243/1.519	0.143	.706
Therapy*Follow-up	-1.104	.906	-2.280/0.671	1.486	.223

Table 4. Differences in the outcome variables in the post-treatment and 12-month follow-up.

Outcome	Post-Treatment			12 month follow up		
	Support	Iconic	χ^2 / t	Support	Iconic	χ^2 / t
Suicide Attempt (C-SSRS)	9 (47.36)	5 (25.00)	$\chi^2=2.199$	2 (13.33)	1 (5.88)	$\chi^2=0.521$
Non-Suicidal Self-injury (DSM-V) N (%)	0 (0.00)	1 (5.00)	$\chi^2=0.975$	1 (6.67)	0 (0.00)	$\chi^2=1.170$
Visits to mental health professionals M (SD)	1.95 (2.99)	1.85 (2.45)	$t=-0.111$	3.80 (5.71)	4.82 (6.21)	$t=0.632$
Satisfaction with therapy (CEQ) M (SD)	34.26 (9.92)	43.40 (6.12)	$t=3.440^{**}$	44.13 (13.61)	47.88 (7.52)	$t=0.947$

Subjective improvement (Individual) <i>M</i> (<i>SD</i>)	global	3.16 (1.01)	3.10 (1.25)	$t=-0.158$	2.73 (1.83)	2.35 (1.17)	$t=-0.709$
Subjective improvement (Family) <i>M</i> (<i>SD</i>)	global	3.42 (0.84)	3.05 (1.19)	$t=-1.120$	2.40 (0.99)	3.12 (1.11)	$t=1.921$

Note : ** $p < 0.05$. Bonferroni correction was applied.

Figures and legends

Figure 1. Flowchart.

Figure 2. Score in the BSL-23 during the three moments of the evaluation in the two treatments.

Supplementary Files

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- [CONSORT2010Checklist.doc](#)