Accepted Manuscript

Accepted Manuscript (Uncorrected Proof)

Title: The Efficacy of Intensive Short-Term Dynamic Psychotherapy with Laser Acupuncture in the Treatment of Moderately Severe Major Depression: A Three-armed Randomized Control Trial

Running Title: ISTDP and LA in the Treatment of Depression in Iran

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To appear in: **Basic and Clinical Neuroscience**

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Abstract

Background: While major depression has been treated with Laser Acupuncture (LA) and Intensive Short-Term Dynamic Psychotherapy (ISTDP), the relative efficacy of these two methods and the combination of the two is unclear. ISTDP is a form of dynamic psychotherapy based on enabling the experience and processing of blocked complex feelings while LA is based on opening of blocked energy meridians.

Objectives: The present study aimed to compare the effectiveness of LA and ISTDP and the combination of the two in the treatment of major depression.

Methods: A randomized controlled trial was carried out with 45 depressed patients on three equal arms (each group: 15 patients): Group I) LA, group II) ISTDP, and Group III) combined LA and ISTDP. Participants were evaluated at six time points using the Hamilton Rating Depression Scale (HDRS), Structured Clinical Interview for DSM Disorder (SCID), and Symptom Checklist-90 (SCL90) including baseline, session 8, session 12, 1-month follow-up, 2-month follow-up, and 3-month follow-up.

Results: HDRS and SCID ratings showed within-group reductions. Both SCL90 and HDRS scores reduced over time in the three groups. At one of the follow-up times, combined LA + ISTDP showed a greater reduction than either individual treatment on the SCL-90 depression subscale but not on HDRS or SCID.

Conclusions: The results of this study indicated that LA and ISTDP, both based on releasing blocked energies, are effective in treating major depression. The combination of the two methods may be more effective in reducing depression symptoms.

Introduction

Depression is one of the main causes of the mental disorder burden, which is estimated to affect 300 million people globally (1). Depression and other mental health disorders are increasing worldwide (2). A World Health Assembly resolution which was adopted in May 2013 has necessitated an all-inclusive, coordinated response to mental disorders at a national level. In addition to causing personal human suffering, depression is correlated with early mortality from suicide and other diseases (3-6). In Iran, the 12-month prevalence of MDD is approximately 12.7% (7).

To treat depression, pharmacological and non-pharmacological interventions are used together to increase the effectiveness of interventions and reduce the likelihood of recurrence of the symptoms (8). However, some side effects of medical interventions such as medication and ECT reduce a person's willingness to use or to continue the course of treatment(9). On the other hand, in some cases, even after completing the course of treatment, patients do not respond to treatment and continue to suffer from depression(10). Therefore, it is necessary to find effective alternative complementary medical and psychological therapies.

Complementary and alternative medicine, either as an adjunct to or as a replacement for conventional therapies, is employed in treating people with depression (11). although their mechanism of action and effectiveness need to be empirically investigated. Acupuncture is a treatment derived from traditional Chinese medicine and has long been used to treat mood disorders making it a candidate alternative to standard anti-depressant medication(12). Acupuncture is presumed to work by the unblocking of energies. A systematic review of twenty-nine studies including 2268 participants showed that the severity of depression was reduced

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significantly with the use of acupuncture, and a meaningful correlation between the number of acupuncture treatments and reduction in the severity of depression was observed (13).

The so-called LA by which laser light is utilized instead of needles to stimulate acupoints has been promoted for almost three decades. Acupuncturists use needles but laser therapists use a more non-invasive laser acupuncture method(14). LA has shown clinically and statistically significant effects in reducing depressive symptoms and patients' emotional distress (15, 16). The effectiveness of LA has been proved in various medical conditions (15-17), but little research, if any, has evaluated its effect on depression with diverse measures for depressive symptoms.

Intensive Short-Term Dynamic Psychotherapy (ISTDP), is a form of psychotherapy that originated from psychoanalytic tenets. ISTDP helps patients process blocked emotions that generate anxiety and self-defeating mental/behavioral reactions (defenses). Blocked emotions are manifested as unique forms of somatic experiences with energy release when they are unblocked and processed during therapy (18). Some studies have shown the efficacy of ISTDP in treating major depression (19-22).

The possibility of increasing ISTDP effectiveness in combination with other treatment modalities like LA is an open question that is addressed in this study. Such a combination is interesting from the theoretical assumptions of ISTDP and LA. Both LA and ISTDP, in fact, work on blocked energies with different rationales and theoretical backgrounds. The two radically different methods of treatment, both may assume the necessity of unblocking energies to heal depression. Both ISTDP and LA may assume that the cause of such a disorder as depression is the blockage. ISTDP assumes the blockage of painful mixed feelings due to attachment trauma, especially from childhood, is the cause of mental disorders like depression while LA assumes the blockage of life

energies is the cause of disorders due to constitution and/or other factors like nutrition, lifestyle, environment, and so on.

ISTDP and LA may operate synergistically to increase the effectiveness of each treatment. A study, for example, evidenced the effectiveness of ISTDP and LA in treating depression in a limited sample (23). ISTDP develops a form of higher-order, integrative self-knowledge (24). It facilitates the experience of blocked emotions that can cause depressive symptoms, while it develops a meaningful understanding of the relationship between blocked emotions and their related defensive reactions that lead to symptoms. ISTDP, in this way, is a form of shuttling back and forth between experiential and reflective self-knowledge (25). Block emotions are energies, and when they are free, they can help patients to have reduced depressive symptoms. On the other hand, LA also works on unblocking energy pathways without symbolizing them as meaningful psychological experiences.

Due to limited research on the use of LA in the treatment of depression and using different complementary treatments along with this modality with unknown effectiveness, more clinical trials with robust methodologies could open a new horizon in the treatment of depression. The questions this current study addresses are 1) whether LA can help treat depression; 2) whether it can increase the effectiveness of ISTDP in treating depression, and 3) whether it can be a suitable substitute for psychotropic medication for depression.

Materials and Methods

Trial Registration and Ethics Review

The study protocol was registered with the Iranian Registry of Clinical Trial (ID: IRCT20111121008146N37) and approved by Shahid Beheshti Medical Science University Authority Research Ethics Board (IR.SBMU.RETECH.REC.1396.1293).

Study Design

This trial used a single-blind, randomized, parallel-group design to examine the efficacy of ISTDP in comparison with LA and the combination of the 2 treatments in depressed patients who were not receiving medication or psychological treatment within the prior three months.

Outcome Measures

The primary measure of effectiveness was the reduction of depressive symptoms measured by the Persian versions of the Hamilton Rating Depression Scale (HDRS) (26). Persian Structured Clinical Interview for DSM Disorder (SCID-II) (27), and Persian Symptom Checklist-90 (SCL-90) (28, 29).

The HDRS and SCID-II were rated by a clinician blinded to the allocation. SCL-90 was rated by the unblinded patient.

Participant Eligibility and Recruitment

Volunteer participants were recruited from the "Insight-New" Psychological Center in Tehran. The inclusion criteria were as follows: the participants had depressive symptoms with a Persian version of the Beck Depression Inventory (30, 31). a score of 12 to 30; they consented to attend a three-

month follow-up after they completed interventions; they could provide informed consent. They were not included in the trial if they were suffering from chronic dysthymia, that is, chronic depression of over two years' duration, hypomania, psychosis, or substance abuse. Furthermore, they were excluded from the study if they had been receiving any psychological treatment or psychotropic medications such as prescribed drugs or herbal supplements in the previous three months. A history of neurological disorders, endocrine disorders, pregnancy, and active suicidal ideation constituted other exclusion criteria. To assess their eligibility, a research assistant who was blind to research allocation subsequently conducted a SCID-II interview with participants. They were excluded if they had any history of psychotic, substance or alcohol abuse, mental retardation and Obsessive-compulsive personality disorder (OCPD), hypothyroidism, and glandular problems.

Randomization and Allocation

We performed a randomized controlled trial on 45 patients with three equal arms (each group: 15 patients): Group I) LA, group II) ISTDP, and group III) LA together with ISTDP. Randomization was performed by using a Block Method to generate a random list of allocations in blocks of 6 (http://www.randomization.com). Patients who were enrolled were randomly assigned by another research assistant, who was uninvolved in the process of eligibility and recruitment, to one of the three groups, according to the randomized list.

Intervention Protocol

Laser Acupuncture

Over the course of eight weeks, twelve interventions were administered by the first author. The first four weeks each consisted of two intervention sessions, and the next four weeks each consisted of one intervention session. The intervention comprised the stimulation of Corporal Points (LI4, LI11, ST36, ST40, BL18, BL20, BL21, SP4, SP6, LIV3, LIV8, LIV14, GB15, GB20, GB34, REN12, REN17, P6, DU20, and HT7) and of Auricular Points (Heart, Stomach, Spleen, Shenmen, Anti-depression, Valium, and Master Omega) determined according to TCM diagnostics, using continuous contact Gallium-Aluminum-Arsenide Laser Acupuncture (GaAlAs), with an average output power of 200 MW, a wavelength of 980 nm, and a dose of 4 J/point for body acupuncture points and 1J/point for ear acupuncture points.

Intensive Short-term Dynamic Psychotherapy

Over the course of eight weeks, twelve treatment sessions were administered by the second author. The first four weeks each consisted of two intervention sessions, and the next four weeks each consisted of one intervention session. The intervention comprised one hour of ISTDP, with a focus on building anxiety tolerance through specific procedures including a graded format, deactivating various defense mechanisms, and experiencing underlying mixed feelings, in the frameworks of the Triangle of Conflict and the Triangle of Person (19). ISTDP in depression operates by overcoming the shut-down of complex feelings and turning inward to guilt-laden rage. The use of pressure (persistent and focused invitation) to experience complex feelings while monitoring the signaling of the anxiety channels and identification and clarification of self-defeating defenses are the key techniques that ISTDP uses to treat depression (32).

Combined ISTDP and LA

This group received both interventions each day, first LA therapy and then ISTDP. The patients of all groups were evaluated six times by the HDRS, SCID-II, and SCL-90 including the pre-test, eighth session, twelfth session, first follow-up (after one month), second follow-up (after two months), and third follow-up (after three months).

Treatment Adherence

The treatment of ISTDP was supervised by the final author and was based on the treatment guide Reaching through Resistance (19). During the project, the second author who provided ISTDP had regular weekly sessions of case supervision. The ISTDP therapist had finished a core training of ISTDP before the project with the training of the final author. The treatment of LA had no supervision since the first author is a supervisor of LA in Iran.

Statistical analysis

Data were analyzed using SPSSv26, and scores of all questionnaires were described with Mean±SD. Normality was checked with the Shapiro-Wilks test. The within-subject evaluation was performed with a paired sample t-test and Wilcoxon test. Comparison between the three groups was done with ANOVA (analysis of variance) and the Kruskal-Wallis test. P-values less than 0.05 were considered significant. No adverse events happened during the treatments.

Results

Of a possible 150 patients at the clinic, 45 were included and randomized (see Figure 1). Demographic information is described in Table 1 for the three groups. The mean age of the patients was 34.89 ± 8.38 years. Regarding gender, 19 (42.2%) of the patients were male. All patients were seen and assessed at each time point.

The results showed in each group: laser acupuncture (1), laser acupuncture with ISTDP (2), ISTDP (3), the HDRS (p-value=0.001, p-value=0.037, p-value<0.001, respectively), SCID (p-value< 0.001, p-value<0.001, p-value= 0.003, respectively) and SCL-90 (p-value<0.001, p-value<0.001, p-value<0.001, respectively) reduced over time within groups. HDRS scores at the eighth session and second follow-up in the laser acupuncture with ISTDP group were lower than the laser group (p-value$_{2,1}$= 0.010, p-value$_{2,1}$=0.011). However, the reduction of SCID score was not significant between the three groups. SCL-90 at the eighth session (p-value$_{2,3}$=0.014, p-value$_{2,1}$=0.011), first follow-up(p-value$_{2,3}$=0.018, p-value$_{2,1}$=0.017) and third follow-up in the laser acupuncture with ISTDP group had lowest score (p- value$_{2,3}$= 0.001, p-value$_{2,1}$<0.001)

The subscales of the SCL-90 including somatization, Depression, anxiety, obsessive-compulsive, interpersonal sensitivity, hostility, phobic anxiety, paranoid ideation, and psychoticism were compared separately within each group over time, and each session was compared between three groups (Table 2).

Discussion

The use of LA alone, ISTDP alone, and the combination of the 2 were all effective at reducing depression on the main measure of HDRS. On the SCL-90 Depression subscale, all three groups also showed improvement but this difference was greater in the third group at 2-time frames compared to the other two groups suggesting the combination of the two may offer an advantage over either treatment alone. Although there were no baseline differences, the ISTDP alone group showed a marked and numerically much larger difference on the primary measure HDRS.

This study provides further evidence that ISTDP is an effective treatment for depression (23). LA had a significant effect on the reduction of self-reported depression symptoms on the Beck Depression scale(18) and HDRS in previous studies (16). The mean HDRS change was 9.28±6.55 in the previous study (16), while this measure evidenced a greater improvement in depressive symptoms in the current study(24). The results in this study regarding the combined effect of both ISTDP and LA are also more robust an in a larger sample in comparison to the previous study. To add more, in this three-armed study, we designed a group with short-term intensive dynamic psychotherapy as a control group. But in the previous study laser therapy and laser therapy combined with dynamic psychotherapy were evaluated (23).

LA may affect many structures and neurotransmitters in the central nervous system, including serotonin, norepinephrine, dopamine, and GABA, as well as the hypothalamus, pituitary, thyroid, and adrenal glands (33-35). A study revealed the effect of LA on the brain of healthy individuals by fMRI brain imaging including LR14, CV14, LR8, and HT7 used in the treatment of depression on the activation of the frontal cortex, limbic and caudal cortex (35), while antidepressants work by modulating the subcortical frontal neural circuits (36).

The mechanism of LA, and acupuncture, is not well understood as a potential antidepressant treatment. Part of the antidepressant effect of this method may include Default mode network

(DMN) modulation or Resting-state network (RSN) modulation (16, 37). Various mechanisms have been proposed for acupuncture, including stimulation of large peripheral nerves, neurovascular bundles, mechanical receptors, or free nerve terminals, but no anatomical neural structure or pathway has been established as a mediator of therapeutic effect (38). Recent attention has been focused on the loss of intermuscular/intramuscular connective tissue, as many meridians and acupuncture points are aligned with this tissue (39). It has also been reported that acupuncture meridians have lower electrical impedance and higher capacitance compared to adjacent controls, which may justify the use of electrical acupuncture. Data are not conclusive (40), however, LA may prove to be an alternative approach to medication for treating depression.

Study limitations include the following five issues. First, unique cultural factors within Iran might affect recruitment and treatment expectations and acceptance. All participants were Iranian, thus, there was no ethnic diversity within the recruited sample. Hence, these results may not be generalizable to other cultures. Second, as a single-blind RCT, therapists and patients could not be blinded to treatment allocations. Thus, outcomes could have been influenced by expectancy effects. Third, since the experimental treatments were delivered by two clinicians, it is unclear if the results are generalizable to other providers. Fourth, the likelihood of allegiance effects (41) may impact outcomes although the blinded rating of depression on HDRS helps to offset this. Finally, the small sample size suggests further research should be done to test the relative efficacy of these treatments alone versus in combination.

Conclusion

ISTDP and LA may appear to be effective treatments for major depression, with a possible added benefit from combining the two treatments. Future studies should include a larger study sample comparative outcome study and process-oriented design to understand how each of these two energy therapies affects the symptom of depression.

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Tables and Figures

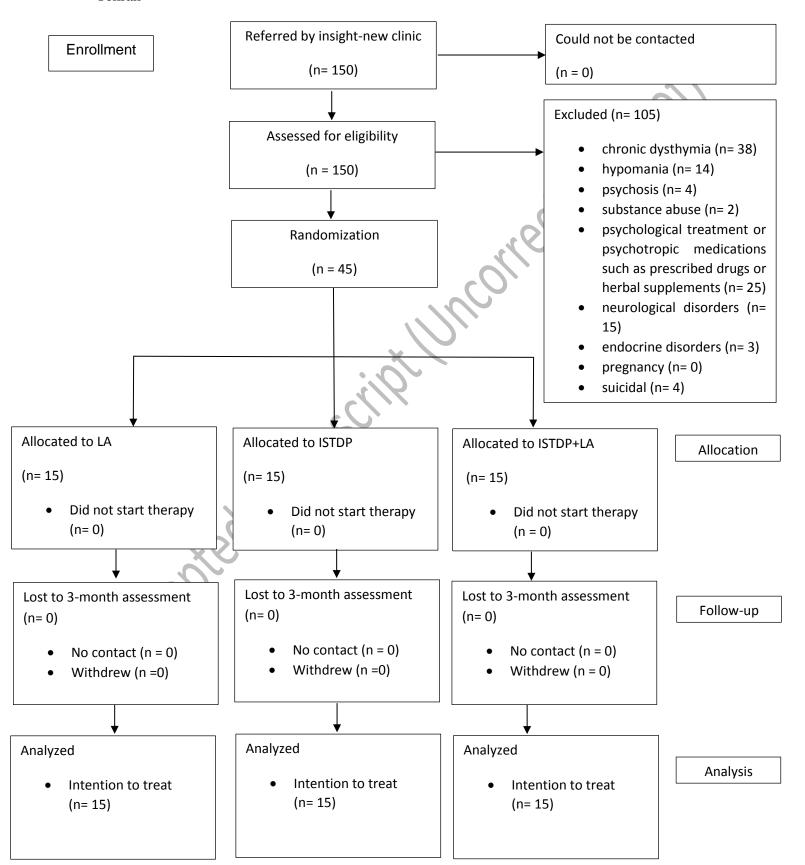**Figure 1.** CONSORT Diagram of patient flow through the study in Tehran insight-new clinic in Tehran

Table1: Demographic characterize of participant in three group

Variable		Laser acupuncture	Laser acupuncture + ISTDP	ISTDP	Between Group p-value
Age		34.60±9.80	34.73±8.46	35.33±7.24	0.969
Sex	male	6(31.6%)	8(42.1%)	5(26.3%)	0.528
	female	9(34.6%)	7(26.9%)	10(38.5%)	
Marital status	1	7(30.4%)	10(43.5%)	6(26.1%)	0.274
	2	8(38.1%)	4(19.0%)	9(42,9%)	
	3	0(0%)	1(6.7%)	0(0%)	
Educational status	2	0(0%)	2(40%)	3(60%)	0.521
	3	7(38.9%)	6(33.3%)	5(27.8%)	
	4	8(36.4%)	7(31.8%)	7(31.8%)	

Table 2: Comparing the component mean scores of the Symptom Check List 90 for the three groups

Variable		Laser acupuncture	Laser acupuncture + ISTDP	ISTDP	P value
Somatization	Pre-test	33.93±6.49	30.27±7.01	33.90±9.61	0.354
	Eighth session	32.06±12.34	23.67±7.85	28.07±9.16	0.115
	Twelfth session	28.67±9.80	27.33±11.07	23.40±7.68	0.251
	First follow-up	25.80±5.05	24.33±5.92	23.33±7.59	0.655
	Second follow-up	24.47±4.78	23.27±4.99	22.73±6.82	0.595
	Third follow-up	25.27±4.49	23.00±4.61	22.73±7.09	0.340
		0.005	0.032	0.001	
Depression	Pre-test	45.53±13.67	36.80±14.67	39.40±11.58	0.209
	Eighth session	35.47±14.74	24.20±8.66	34.20±11.79	0.016
	Twelfth session	31.13±15.42	23.00±10.28	28.27±10.06	0.065
	First follow-up	30.53±13.91	23.53±13.24	28.40±8.94	0.023
	Second follow-up	20.93±9.49	23.80±12.60	26.40±9.76	0.067
	Third follow-up	25.60±12.99	14.67±2.22	21.87±4.68	0.0001
		0.0001	0.0001	0.0001	
Anxiety	Pre-test	23.67±7.69	19.93±4.37	23.80±6.53	0.262
	Eighth session	20.60±9.71	16.13±5.46	18.67±4.99	0.196
	Twelfth session	17.20±7.61	16.87±7.19	16.23±6.71	0.918
	First follow-up	17.67±3.18	16.33±4.25	17.20±5.51	0.714
	Second follow-up	18.53±4.03	18.60±4.53	17.60±5.69	0.950
	Third follow-up	18.00±4.09	16.40±5.44	17.07±4.20	0.573
		0.018	0.010	0.005	
Obsessive Compulsive	Pre-test	29.80±10.14	26.53±4.97	32.27±7.12	0.092
	Eighth session	26.33±9.68	22.27±7.60	26.40±6.50	0.291
	Twelfth session	25.07±10.82	22.27±8.88	21.67±7.67	0.662
	First follow-up	21.00±3.46	18.93±3.53	18.73±4.33	0.189
	Second follow-up	22.40±5.02	21.53±3.81	21.33±6.29	0.563
	Third follow-up	21.53±4.56	21.20±3.61	21.20±6.53	0.986
		0.246	0.001	0.0001	
Interpersonal Sensitivity	Pre-test	29.00±7.79	25.87±4.39	29.43±7.48	0.625
	Eighth session	26.33±9.48	21.40±5.54	26.27±8.62	0.456
	Twelfth session	23.20±9.16	20.07±7.28	19.93±7.99	0.466
	First follow-up	18.60±4.21	16.40±5.45	15.93±6.08	0.381
	Second follow-up	18.60±3.64	17.73±3.84	16.53±5.28	0.299
	Third follow-up	17.20±3.69	16.00±4.76	16.80±5.12	0.711
		0.0001	0.0001	0.0001	
Hostility	Pre-test	17.67±7.39	14.66±5.15	18.47±4.53	0.217
	Eighth session	14.87±7.26	12.63±3.51	14.00±3.06	0.670
	Twelfth session	13.47±7.08	11.47±4.63	11.27±4.95	0.819
	First follow-up	12.67±2.87	10.60±2.16	9.67±2.58	0.017
	Second follow-up	13.27±3.51	11.13±3.23	11.27±3.47	0.184
	Third follow-up	12.53±3.74	11.13±3.56	11.33±2.79	0.432
		0.031	0.344	0.0001	
Phobic Anxiety	Pre-test	14.47±6.08	13.60±3.60	14.73±3.77	0.684
	Eighth session	13.73±6.17	12.13±5.11	13.53±4.64	0.498
	Twelfth session	12.67±4.29	13.93±5.97	12.40±4.79	0.748
	First follow-up	16.13±3.54	15.00±2.85	16.00±4.07	0.605
	Second follow-up	16.86±4.34	14.86±3.16	14.13±5.15	0.146
	Third follow-up	17.20±4.09	14.93±3.19	14.20±4.47	0.124
		0.001	0.097	0.213	

Paranoid Ideation	Pre-test	17.67±6.95	14.87±4.84	19.47±6.40	0.158
	Eighth session	16.67±7.99	13.73±4.38	16.20±4.97	0.410
	Twelfth session	14.47±6.38	13.47±5.28	13.47±4.52	0.973
	First follow-up	11.80±2.18	11.40±1.95	11.67±2.19	0.791
	Second follow-up	13.40±3.46	11.07±3.81	12.40±2.29	0.251
	Third follow-up	12.60±1.92	13.06±3.06	11.67±4.61	0.428
		0.085	0.483	0.0001	
Psychoticism	Pre-test	22.73±6.65	20.47±5.04	23.60±6.07	0.420
	Eighth session	22.20±8.73	17.93±5.31	20.47±5.73	0.433
	Twelfth session	20.47±9.08	18.00±5.37	17.93±5.16	0.878
	First follow-up	19.93±2.96	20.33±4.73	19.73±6.28	0.862
	Second follow-up	19.33±6.43	16.67±5.25	18.53±5.03	0.506
	Third follow-up	20.60±5.27	18.73±5.03	19.93±5.67	0.632
		0.165	0.038	0.027	