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COMPARATIVE STUDY METACOGNITIVE THERAPY VERSUS CLOMIPRAMINE AND COMBINED THERAPY IN THE IMPROVEMENT OF OBSESSIVE-COMPULSIVE AND ANXIETY SYMPTOMS IN PATIENTS WITH OBSESSIVE-COMPULSIVE DISORDER (OCD): A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Background: The aim of this study was to compare the efficacy of metacognitive therapy (MCT), Clomipramine and the combination of MCT with Clomipramine treatment in treating Iranian patients with OCD. **Methods:** This randomized clinical trial was conducted at referring to psychological- psychiatric centers of Tehran, Iran, from November 21, 2014 to January 20, 2015. Thirty nine outpatients meeting DSM-IV-TR criteria for OCD without any other axis I and II disorder were randomly assigned to one of three treatment conditions: MCT, Clomipramine and combined treatment. All the patients received 10 weeks of treatment. TheYale-Brown Obsessive-Compulsive Scale (Y-BOCS) and Beck Anxiety Inventory (BAI) were administered at pre-treatment and post-treatment. Data were analyzed by Kruskal Wallis test, clinically significant change, ANCOVA and pre- to post-treatment percentage improvement. **Results:** Results showed that the amount of reduction in symptoms of obsessive-compulsive was (%39.2) in the drug therapy group, in the meta-cognitive therapy group (%52.6) and in the

combination group (%56.5) while reduction in level of anxiety in the medical treatment group was (%57.1), in the drug therapy group (%63.8) and in the combination therapy group (%59.6). All results were statistically significant (p = 0.01). There was clinically significant change results also showed that, unlike the Clomipramine, the MCT and combined treatment lead to more improvement in 10 weeks. **Conclusion:** MCT and combined treatment are more effective than Clomipramine. However in this study, due to the short duration of treatment and lack of prescription of medication with a maximum effective dose, the drug's efficacy results could not be generalized and long-term follow-up studies in this area is necessary to examine the problem more carefully.

KEYWORDS: Obsessive-compulsive disorder; Metacognitive model; Metacognitive therapy; Clomipramine.

INTRODUCTION

Obsessive-compulsive disorder (OCD) is a severe mental disorder with a prevalence of approximately 2-3% of the general population.[1, 2] and the World Health Organization knows it as the tenth cause of disability[3, 4] with an onset at the age of 18 in %80 of cases.[5] This disorder is related to impaired social functioning and low quality of life.[6]

Meta-cognition is a multi-dimensional concept and refers to the knowledge and belief of the thinking and strategies that people use them to control their thinking processes. This concept includes the knowledge, processes and strategies and approaches to assess, monitor and control the knowledge.[7, 8] Unlike cognitive approaches, meta-cognitive therapy, regardless of the content of obsessions, focuses solely on meta-cognitive beliefs and does not attempt to balance other areas of beliefs.[9]

In a case report examined the effect of cognitive therapy on a patient with OCD. After meta-cognitive treatment, the subject's score in Obsessive-Compulsive Scale of Yale - Brown was 30 scores lower and patient's anxiety, depression and stress decreased. These results continued during three to six months of follow-up after treatment.[10] The same study showed the symptoms of obsession, anxiety, depression, stress, self-efficacy, meta-cognitive beliefs and thought control improved significantly and continued during the next three months of follow-up.[11] Another research showed that the meta-cognitive and combination of meta-cognitive and Fluvoxamine therapy, compared to treatment with Fluvoxamine, leading to a significant improvement in obsessive-compulsive symptoms, depression and anxiety.[12]

Because of the lack of specific research on comparative study of cognitive therapy and pharmacotherapy in OCD, this study was performed to compare the effects of meta-cognitive therapy, treatment with Clomipramine, and combination therapy (meta-cognitive therapy and treatment with Clomipramine) to improve the symptoms of OCD and the overall level of anxiety.

METHODS

This randomized clinical trial was conducted at referring to psychological- psychiatric centers of Tehran, Iran, from November 21, 2014 to January 20, 2015. In this clinical trial, stratified randomization was used with the baseline OC symptoms of the participants. For this, all participants were divided into three groups, i.e meta-cognitive, synthetic and Clomipramine.

Inclusion criteria were having diagnostic criteria for OCD, lack of receiving any psychological treatment and medication (at least one months before entering the study), age of 18-50 years and having junior education. Patients with symptoms of psychosis, substance abuse, other disorders of axis I and II (with the exception of personality impairment of obsessive - compulsive) were excluded from the study.

After giving adequate explanation of research, subjects gave their written consent before entering the study. This research was confirmed regarding compliance with ethical issues at the ethical committee of the University of Welfare and Rehabilitation Sciences of Tehran. To collect data, in addition to demographic questionnaire that was used to obtain demographic information of subjects, the following questionnaires and scales were used

Clinical version of The Structured Clinical Interview for Axis I Disorders (SCID-I / CV)

A standard tool for the assessment of psychiatric disorders, based on DSM-IV definition, is one which is set for research and clinical purposes. Implementation of SCID-I / CV requires clinical judgment of interviewer on the interviewee's response, so the interviewer should have sufficient knowledge and experience in psychopathology. According to various research reports, validity and reliability of this tool is acceptable. For example, in the diagnostic reliability between raters, its 'Kappa index was reported 0.7.[13] In a study Persian version of the SCID-I /CV had the validity of this tool by was confirmed by experts and professors of clinical psychology and a week later 0.95 test-retest reliability was reported.[14, 15]

Structured Clinical Interview for Axis II Disorders in DSM-IV (SCID- II)

It is a structured diagnostic interview to assess personality disorders with 119 items. In a study to determine the reliability and within two weeks on 284 subjects in four psychiatric centers and two non psychiatrist consultants, the overall kappa coefficient for psychiatric patients was 0.53 and an amount from 0.24 for obsessive-compulsive personality disorder to 0.74 for histrionic personality disorder was obtained. The agreement between assessors was lower in non psychiatrist patients (general Kappa 0.38).[16] In study of Bakhtiari (2000), the Persian version was approved by several professors of Clinical Psychology and the reliability value of 0.87 was reported within a week.[15]

Y-BOCS Scale: The Obsessive-Compulsive Yale - Brown Scale is a 10-itemes scale used to assess the severity of obsessions and compulsive behavior independently of the content and number of symptoms which is graded by a 5-point scale from 0 to 4. Scores range from 0 to 40. There are 5 classifications for these scales including: subclinical = 0-7, mild=8-15, medium = 16-23, severe= 24-31, very severe = 32-40. Scores are to measure 5 signal characteristics: (1) the duration and frequency, (2) interference with job and social functioning, (3) distress, (4) the degree of resistance, (5) the degree of control of obsession and compulsion. The scale maintains a high content validity, test-retest reliability and internal consistency.[17] Sabouri et al. in a study of patients with obsessive- compulsive disorder reported a validity and reliability of 0.98 and 0.89, respectively.[18]

Beck Anxiety Inventory (BAI)

This questionnaire has been designed to measure anxiety and includes 21 phrase. Each phrase reflects one of the symptoms of anxiety that is experienced by people who are clinically anxious or who are in a state of great anxiety. One should read the list of symptoms and order them quantitatively. Range of changes differs from zero to 63, and high scores indicate more severe anxiety. The scale has a good test-retest reliability (α=0.75, within 1 week after first use), internal consistency (0.87) and acceptable validity. Cronbach alpha was reported 0.92.[19] In a study from Iran, the Cronbach alpha of 0.92 Iran has been reported.[20]

Intervention: The basis of meta-cognitive therapy is implementation of incremental meta-cognition pattern of Wales that runs a total of 10 sessions. During these sessions, meta-cognitive skills, including fair comprehensive awareness, exposure and response prevention, confrontation and respond, postponing concerns and verbal challenges are taught.[21 and 22]

In the first session, after initial evaluation of patients, the conceptualization of case, introduction to the treatment, suppression of ideas and impartial comprehensive awareness training was done and then subjects were asked to used impartial comprehensive awareness technique whenever faced with troublesome thoughts as a duty, that is merely view their though course without any attempt to interpret or explain, control or react to it.

In second session, teaching implementation of more neutral universal consciousness techniques were on the agenda and to enhance the meta-cognitive awareness of patient and non-involvement of patients with anxiety and daily rumination, the technique of exposure and response and postponing concern was instructed to the patient.

Exposure and response technique allows the patient to fulfill his rituals, but the purpose of engaging in compulsive rituals is corrected, that is, instead of engaging in obsessive rituals to get rid of thoughts or to reduce the related risks, patient is required to only go on with his obsessive rituals while maintaining awareness of his obsession with his thoughts. Regarding the technique of postponing concerns, patient is told to know that whenever disturbing thoughts are appearing, they should be concerned as merely thoughts and it is not necessary to think about them now or worry about their consequences and get himself busy with rumination, rather he shall think about them actively later and let these thoughts gradually disappear over time. However, the patient will be asked to actively think about his concerns for 15 to 30 minutes every night. At the end of the second session, the patient was told to use impartial mindfulness techniques, exposure and response and postponing concerns technique as his homework.

In the third and fourth sessions, other inefficient strategies and beliefs about the patient's thought fusion were recognized and challenged by using cognitive techniques. Other solutions which were practiced in these two sessions along with more practice of impartial comprehensive awareness, exposure and response and postponing concerns, included using behavioral tests in sessions and between them to challenge correctness of thought fusion beliefs.

In the fifth and sixth sessions, in addition to the above practicing techniques, patients' belief regarding the necessity of accommodating with their obsessive behaviors were studied and to challenge these belief, controlled experiments of exposure response prevention (ERP) were used.

In the seventh and eighth sessions by using verbal methods and observation of behavior, unsolved reference beliefs and obsessive behaviors were challenged and with the discovery of signs and stop criteria of obsessive practice, therapist helped the authorities to change these symptoms and criteria.

In the last two sessions, work began on the overall treatment plan. The overall project includes an example of the formulation of cases, a list of meta-cognitive beliefs of patient about thoughts and disturbing impulses and a summary of evidence that were resulting from the verbal and behavioral techniques and that had been challenged by patient.

Treatment with Clomipramine includes using this drug at a dose of 50 to 150 mg per day for 10 weeks which after discussing the patient's physiological problem, effects and method of taking the drug, it was prescribed by the psychiatrist in the first session and the right amount was given.

In the next meeting a general evaluation of patient was done and after examining the effect of the drug and concerns of patient, he was encouraged to use drugs regularly until the end of treatment.

In combination therapy, after each meta-cognitive therapy session, participants had a short visit with their psychiatrist so that they could receive their drugs or their drugs were examined. In this study, descriptive statistics were used to describe, collect and classify information obtained from the sample. Also, the analysis of covariance (ANCOVA) was used for comparing the 3 groups (medication, psychotherapy or a combination) by removing the effect of pre-test and t-test for independent groups to compare the mean scores of pre-test and post-test. To test the hypothesis, the significance level of 0.05 is considered.

To compare the rate of improvement in Y-BOCS scores of subjects in the three groups, criteria for clinically meaningful change and the asymptomatic situation was used.

In the criteria for clinically meaningful change, if one has at least 10 points in Y-BOCS scores at the end of treatment he is said to achieve the sustainable progress and if his Y-BOCS score are 14 or lower, he is said to have achieved remission criteria.

If a person does not achieve the sustainable change criteria, he will be classified as unchanged and if patients score a minimum of 10 at the end of treatment, he will be classified

as damaged. Regarding the criteria of lack of any sign, it is necessary to receive 7 or lower grade at the end of treatment.[23]

RESULTS AND DISCUSSION

Of 39 participants in the study, 13 subjects in the meta-cognitive therapy group, 13 subjects in the treatment with Clomipramine group and 13 subjects in combination therapy group were treated. Two subjects in treatment with Clomipramine group were excluded from the study due to drug side effects and as a change in drug after 6 sessions of treatments. One of the subjects in the combination group was excluded from the study due to drug side effects and change in drug after 5 sessions. One of the combination therapy group members and two patients in meta-cognitive therapy group were excluded due to not paying any visit. Meta-cognitive therapy group consisted of seven women and four men, combination therapy group included nine women and two men, and treatment with Clomipramine was composed of eight women and three men. Five of the cognitive therapy group and six experimental group members and one subject of Clomipramine were single and the rest were married. Due to the proximity of many of the variables in the three groups, it seems that the research groups had no significant difference. The mean and standard deviation of subjects and Kruskal-Wallis test for variables before treatment is given in Table 1. Since the results did not show a significant difference between the groups, so it can be said that even before introducing the intervention, groups were homogeneous in these variables.

Table 2 Shows Kruskal-Wallis test and covariance analysis of variables after excluding the effect of pre-test at the end of treatment. Looking at the average grade of the variables at the beginning and end of treatment, it seems that all three therapies has led to improvement in conditions of patients, but the effects of treatment in meta-cognitive therapy group and the combination one is more.

According to Table 3, the difference between the effectiveness of treatment on symptoms of obsessive - compulsive disorder between meta-cognitive therapy and drug therapy treatment and between combination therapy and drug therapy is significant, but it is not significant between meta-cognitive and mix method group. Differences in treatment efficacy between three groups were not significant on the overall level of anxiety.

The overall average severity of obsessive-compulsive symptoms in patients based on the cut-off points (0-7 non-clinical, 5-18 mild, 16-23moderate, 24-31sever and 32-40 very severe) at

the clinical and severe (Y-BOCS = 26.9) and anxiety on the basis of cut-off points (0-7 partial, 8-15 mild, 16-25 moderate and 26- 63 severe) were moderate (BIA = 24.5), respectively.

The amount of reduction in symptoms of obsessive-compulsive was (%39.2) in the drug therapy group, in the meta-cognitive therapy group (%52.6) and in the combination group (%56.5) while reduction in level of anxiety in the medical treatment group was (%57.1), in the drug therapy group (%63.8) and in the combination therapy group (%59.6). All results were statistically significant (p = 0.01).

According to the results of a patient in a drug treatment group (%9.01), 7 patients in the meta-cognitive therapy group (%64) and 7 patients in the combination group (%64) achieved an improvement criteria. 4 patients in the drug therapy group (%36), 9 patients in the meta-cognitive therapy group (%81) and 9 patients in the combination group (%81) achieved stable progress.

7 patients in the drug therapy group (%64), 2 patients in the meta-cognitive therapy group (%19) and 2 patients in the combination group (%19) did not change.

Table 1: Prevalence and demographic data of the participants in research

Statistical index		Drug therapy		Psychotherapy		Combination therapy		
		Frequency (average)	Percent (SD)	Frequency (average)	Percent (SD)	Frequency (average)	Percent (SD)	P-value
Gender	Male	3	27.27	4	36.37	2	18.18	0.76
	Female	8	72.73	7	63.63	9	81.82	
Marital status	Single	1	9	5	45.5	6	54.5	0.55
	Married	10	91	6	54.5	5	45.5	
Age		29.818	7.152	29.636	10.141	28.272	8.319	* 0.603
Education		13.545	4.39	13.454	2.805	12.09	2.7	*1.13
years of disease		4.818	2.676	4.363	3.854	4.454	2.252	0.*803
* Kruskal-Wallis test								

Table 2 .The mean standard deviation and the Kruskal-Wallis test for variables and the overall level of anxiety and obsessive-compulsive symptoms before treatment and after treatment

Statistical index		Drug therapy		Psychotherapy		Combination therapy		
Pre-treatment	Obsessive-compulsive symptoms	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	χ^2

	Overall level of anxiety	25	5.761	27.909	3.33	27.818	4.556	1.549
Post-treatment	Obsessive-compulsive symptoms	24.363	9.962	24.363	12.01	24.818	7.45	0.15
	Overall level of anxiety	15.272	4.67	13.272	4.88	12.09	2.736	1.48
		10.454	5.538	8.818	5.016	10	4.735	0.23

Table 3. The results of the analysis of interventions on symptoms of anxiety and obsessive – compulsive

The purpose of the study	**Obsessive-compulsive symptoms**		**The overall level of anxiety**	
	F	**P**	**F**	**P**
comparison of the effects of Clomipramine and meta-cognitive therapy	7.44	0.013	1.011	0.327
comparison of the effect of Clomipramine, and combination therapy	12.386	0.002	0.128	0.724
comparison of the effect of cognitive therapy and combination therapy	0.492	0.492	0.526	0.477

DISCUSSION

At the beginning of the study, it was predicted that the combination therapy and meta-cognitive and Clomipramine would lead in significant decrease in scores of patients with OCD obsessive – compulsive at Beck Anxiety Inventory and Yale – Brown questionnaire. The results show that there is a significant difference between the mean scores of obsession and both meta-cognitive and combination methods are more effective. The difference between Clomipramine and combination therapy and meta- cognitive therapy and combination therapy on the overall level of anxiety of patients is not significant.

The most effective way to treat symptoms of obsessive – compulsive disorder in patients was addressed and according to the diagram, combination therapy has a faster slope than other treatment methods. Therefore, concerning reduction in signs and also with respect to the visual comparison between graphs of 3 treatment methods, it was found that effectiveness of the combination therapy is more obvious than others.

It was also seen that reduction in the overall level of anxiety in meta-cognitive therapy has a higher slope than the other two methods. Therefore, for reducing the signs and with respect to the visual comparison between graphs of 3 methods of therapy, meta-cognitive therapy has a higher effectiveness than other methods. Findings in the present study demonstrated the

effectiveness of triple therapies on obsessive - compulsive disorder, which is consistent with other research on the efficacy of meta-cognitive therapy as well.[25, 133-135]

Anduz (1385) in a single case study showed that meta-cognitive therapy in OCD treatment will lead to reduction in score of patient in the Yale-Brown scale of obsessive –compulsive. The findings of which is consistent with results of this study.[10]
Firoozabadi and Shareh (1388) tried to evaluate the efficacy of the meta-cognitive treatment of OCD using impartial comprehensive awareness technique in a course of 8-week sessions. In their study, at the end of treatment %66 improvements in Y-BOCS scale and % 62 for anxiety was observed that make no significant difference in terms of improvement percentage obtained in the present study.[11]

Another study by Shareh, Gharaie, Atefvahid and Eftekhar (2010) showed that compared to treatment with Fluvoxamine, meta-cognitive therapy and combination therapy (meta-cognitive and Fluvoxamine) would led to a significant improvement in the symptoms of obsessive - compulsive and anxiety, and analysis of variance with repeated measures for each group alone indicated faster effectiveness of meta-cognitive and combinations therapy than the Fluvoxamine, where finding in the present study were consistence, but the percentage of improvement obtained with meta-cognitive therapy in Y-BOCS scale had been 100%.[12] Hence, the difference may be due to the low sample size and duration of disorder in samples of the study.

Of course, differences in exclusion criteria of two studies, such as co-morbidity with depression-anxiety disorders that were considered as exclusion criteria in current study but inclusion ones in Shareh and colleagues' and the difference in results for different types of obsession and compulsion could be effective in final results.

This approach is inefficient and can be cognitive therapy to reduce the severity of obsessive - compulsive and anxiety until the effectiveness of the medication used.

With regard to the efficacy of meta-cognitive therapy and combination therapy being similar in all cases and no significant difference between these two approaches found in any of the instruments, and due to the number of patients achieving remission criteria being quite similar in the two treatment approaches, this discussion about all of the research hypotheses, could be well generalized to concurrent meta-cognitive and pharmaceutical therapy.

Regarding the effectiveness of combination therapy, compared to psychotherapy and drug therapy alone, various studies indicate that often using a combination of medication and psychological (especially behavior therapy), is most effective in the treatment of OCD than psychotherapy or pharmacotherapy alone.[23, 84-85]

CONCLUSION

The findings of this study suggest that there was no significant difference in any of the variables between the metacognitive therapy and combination therapy. Other research in this field has found conflicting results where some findings are consistent with others and others are not.

However in this study, due to the short duration of treatment and lack of prescription of medication with a maximum effective dose, the drug's efficacy results could not be generalized and long-term follow-up studies in this area is necessary to examine the problem more carefully.

Since there are no significant differences in effectiveness of meta-cognitive therapy with combination therapy, and regarding the meaningful difference between these two approaches as compared to therapeutic efficacy of Clomipramine in 10 weeks duration, it seems that higher effectiveness of meta-cognitive therapy and combination therapy in improving the symptoms of obsessive -compulsive disorder is due to changes resulting in insufficient beliefs and meta-cognitive strategies of patient and this therapy can be used to reduce the severity of obsessive – compulsive symptoms and anxiety of the patient until the drugs take effect.

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