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The effect of the eye movement desensitization and reprocessing intervention on anxiety and depression among patients undergoing hemodialysis: A randomized controlled trial

Running title: EMDR and hemodialysis patients

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Abstract

PURPOSE: This study investigated the effect of the eye movement desensitization and reprocessing intervention on depression and anxiety levels in patients undergoing hemodialysis.

DESIGN AND METHODS: In this randomized controlled trial, ninety patients were enrolled. The intervention group received six sessions of eye movement desensitization and reprocessing therapy. Data was collected prior to and two weeks after the intervention using the Hospital Anxiety and Depression Scale.

FINDINGS: Measured levels of anxiety and depression were significantly lowered in the intervention group compared to pre-intervention results and to the control group.

PRACTICE IMPLICATIONS:

Eye movement desensitization and reprocessing should be considered a complementary and alternative treatment for the reduction of depression and anxiety in patients undergoing hemodialysis.

Keywords: anxiety, eye movement desensitization and reprocessing, depression, hemodialysis, nursing

INTRODUCTION

Patients with end-stage renal disease (ESRD) have a renal function that cannot sustain life without kidney transplantation or replacement therapies such as hemodialysis. It has been reported that one million patients across the world are undergoing maintenance hemodialysis. Also, it has been estimated that by 2030 this number will exceed two million indicating a global health challenge (Bujang, Adnan & Hashim, 2017). Patients with ESRD on lifelong maintenance hemodialysis have complex healthcare needs related to the physical and psychological effects of ESRD, its treatment and comorbidities (Davaridolatabadi & Abdeyazdan, 2016).

Psychological issues among hemodialysis patients

Adherence to the hemodialysis regimen requires that the patient adapts to a number of life affecting restrictions such as fatigue and lack of energy, sexual dysfunction, fluid and diet control, fistula cannulation, and frequent hospital readmissions (Delmas et al., 2018; Smith, 2016). Since the process of hemodialysis often limits patients' ability to carry out activities of daily living (ADLs) plus financial challenges (Kutner, Zhang, Allman & Bowling, 2014), high levels of mental stress is often experienced by them (Gerogianni & Babatsikou, 2013). Psychological issues such as anxiety, depression and suicidal ideation are prevalent among

patients with ESRD and increase in proportion to the degree of renal decline (Jhee et al., 2017). These psychological issues are associated with a poor quality of life (QoL) (Gerasimoula et al., 2015), increased rate of hospital readmissions and longer lengths of hospital stay (Najafi, Keihani, Bagheri, Jolfaei & Meybodi, 2016). The consequences of hemodialysis such as fatigue and loss of appetite can make it difficult to differentiate anxiety and depression from the physical effects of treatment (Picariello, Moss-Morris, Macdougall, & Chilcot, 2017). While anxiety and depression are common in hemodialysis patients, they are often not diagnosed. Therefore, failure to diagnosis anxiety and depression may result in treatment non-compliance or physical presentations including palpitations and indigestion (Cohen, Cukor & Kimmer, 2016).

Ng, Tan, Mooppill, Newman and Griva (2015) described a 44.7-54.1% prevalence of depression and anxiety in hemodialysis patients following a 12-month study (n=159). Depression is associated with sorrow, helplessness, despair, guilt, sleep disturbances, decreased appetite and sexual desire disorders (Cohen et al., 2016). Depression can reduce health-related QoL and adversely affect morbidity and mortality in hemodialysis patients (Preljevic et al. 2013). Najafi, et al., (2016) reported a high prevalence of untreated depression in patients on maintenance hemodialysis, with over 70% of patients demonstrating indices of depression and anxiety. However, it was noted that patients were unaware of their symptoms and did not acknowledge any need for treatment. Liu et al. (2018) in a study of 194 older patients receiving maintenance hemodialysis reported that 45.9% of these patients experienced depressive symptoms and contended that the severity of symptoms and degree of inability to undertake ADLs were the major causes of depressive symptoms. Additionally, there are biologic mechanisms that cause poorer medical outcomes in patients with depression; for instance, depression can lead to an increase in inflammation, that accelerate atherosclerosis and an increased risk of cardiovascular diseases (Shirazian et al., 2017). If hemodialysis guidelines do not screen patients routinely for mental health issues, the potential to detect depression and anxiety is reduced. Untreated mental health illness contributes to increased morbidity and mortality, reduced QoL and increased risk of suicidal ideation of this patient group (Fan et al., 2014).

Methods to treat anxiety and depression in hemodialysis patients

Pharmacological and non-pharmacological treatments can be used to reduce anxiety and depression in hemodialysis patients (Grigoriou et al., 2015). Drugs used for relieving anxiety and

depression have many side effects such as increased levels of toxic metabolites in the blood, cardiovascular disorders, anorexia and vomiting, hepatotoxicity and risk of bleeding (Rezaei et al., 2015). Patients on hemodialysis are at a particular risk of altered pharmacokinetics. For instance, due to renal impairment, drug clearance is impaired and suitable dosage adjustment, care with prescription timing and careful monitoring of medication are essential (Cohen et al., 2016). Whilst current guidelines recommend the use of a selective serotonin reuptake inhibitor to treat depression in this patient group, there is a paucity of evidence related to the use of antidepressant medications. Additionally, there is no conclusive data on the relative risks and benefits of such drug use (Palmer et al., 2016). Therefore, non-pharmacological methods are preferable to pharmacological methods for relieving depression and anxiety in hemodialysis patients due to the low risk of side effects, low costs and limited potential for drug dependency (Grigoriou, Karatzaferi & Sakkas, 2015). Concerns about drug-induced side effects in hemodialysis patients have increased interests in the use of psychological therapies and complementary and alternative medicine approaches. It has been shown that nonpharmacological methods such as meditation, hypnotism, progressive muscle relaxation and cognitive behavior therapy (CBT) (Duarte et al. 2016), and regular exercise (Rezaei et al. 2015) can reduce anxiety and depression in hemodialysis patients. The use of relaxation interventions such as Benson's relaxation has been shown to prevent further health-related complications in hemodialysis patients through reducing anxiety and stress (Otaghi, Borji., Bastami, & Solymanian, 2016). Hemodialysis patients who have received acupuncture on a regular basis demonstrate significant reductions in depression, anxiety and general psychological distress compared to the control group (Hmwe, Subramanian, Tan & Chong, 2015). Grigoriou et al., (2015) argue that the treatment of depression in hemodialysis patients should be a multidimensional approach with the use of different strategies drawing on the skills of the whole healthcare team. Nurses are responsible for the provision of mental health care alongside physical care and their role includes patients' education to improve their mental health and prevent psychological problems (Happell, Platania-Phung & Scott, 2013). One of the nonpharmacological therapeutic interventions that can be used by nurses is the Eye Movement Desensitization and Reprocessing (EMDR) therapy.

Eye Movement Desensitization and Reprocessing (EMDR) therapy

EMDR is an inexpensive, safe and non-invasive treatment that has been endorsed by the American Psychiatric Association (Shapiro & Threlfo 2002). In 2013, the World Health Organization (WHO) recognized EMDR as a psychotherapy intervention for the treatment of post-traumatic stress disorder (PTSD) (Valiente-Gomezet al., 2017).

The underpinning assumption of EMDR therapy is that anxiety as the product of distressing events have not been properly processed by the nervous system, leading to isolated neurobiological stasis (Shapiro 2002). This therapy has been developed initially for the treatment of PTSD and is guided by the use of a behavioral-cognitive technique on the basis of the adaptive information processing model (Amano & Toichi 2016; Mazzola et al., 2016). Distressing unprocessed events can lead to prolonged negative consequences such as anxiety and depression. Therefore, the aim of EMDR is to process and resolve any such underlying unprocessed events, that may cause negative mental consequences (Oren & Solomon, 2012).

The guided eye movements used in EMDR immediately activate the parasympathetic nervous system and lead to physiological responses (Lee & Cuijpers, 2013). During EMDR, alternating left-right simulation of the brain by eye movements, sounds or taps is sought, although the mind is focused on troublesome issues in life for stimulating the blocked or frozen information processing system (Benor et al. 2016; Marofi, Maroufi, Zamani-Foroshani, Allimohammadi, & Izadikhah, 2016). The patient is asked to focus on the causes of negative life issues and their consequences, whilst simultaneously is attending to the alternate stimulus producing eye movements or other forms of bilateral stimulations (Oren & Solomon 2012). While the patient focuses on a memory or negative experience, he/she is asked to report new thoughts that have emerged in an iterative process until the memory or experience is no longer experienced as distressing (Shapiro, 2014).

Schneider et al. (2005) state that EMDR is a significant treatment for reducing depression and anxiety. Behnammoghadam, Alamdari, Behnammoghadam, & Darban (2015) and Hase et al., (2015) reported statistically significant reductions in the depressive symptom of patients after the use of EMDR. Staring et al. (2016) compared the effects of EMDR and Competitive Memory Training (COMET) used in combination in patients with anxiety (n=47). They indicated that the use of EMDR therapy mediated reductions in anxiety and depression symptoms. However, COMET was associated with more improvements in self-esteem. The use of EMDR therapy has

demonstrated positive effects on patients with PTSD (Sadeghi et al. 2015), QoL in patients with myocardial infarction (Salehian et al., 2016) and pre-operative anxiety in children (Marofi, Marofi, Zamani-Foroshani & Izasikhah, 2016). Chen, Zhang and Liang (2015) following a systematic review compared EMDR and CBT in adult patients with PTSD and suggested that EMDR could be more suitable for this patient group. Valiente-Gomez et al. (2017), following a systematic review of randomized controlled trials (RCTs) that used EMDR therapy noted that there were few such studies. They argued that despite the presence of limited evidence, EMDR could be effective in mental disorder related to trauma, psychotic or affective symptoms and chronic pain. Gauhar (2016) reported that after only 6-8 sessions of EMDR in patients with depression, negative thoughts and depressive moods were decreased significantly compared to the control group and reported a maintained improvement in mood at a three-month follow up interview.

No English language literature was discovered on the use of EMDR in hemodialysis patients with anxiety or depression. Rahimi, Rejeh, Karimooi and Tadrisis (2016) reported in Farsi a randomized clinical trial utilizing the Hemodialysis Stress Scale questionnaire (HSS-Baldree) on the effect of EMDR on psychological stress in patients undergoing hemodialysis. They reported that EMDR was beneficial in decreasing patients' stress. The aim of this study was to investigate the effect of EMDR on depression and anxiety levels among hemodialysis patients.

METHODS

Design

This was a randomized controlled trial. Subjects were recruited from high-turnover hemodialysis units in two large tertiary referral teaching hospitals in an urban area of Iran. Data was collected from December 2015 to July 2016.

Sampling

A total of 90 patients were randomly assigned into intervention (n=45) and control (n=45) groups. The sample size estimation was based on the primary outcome data from a previous study (Arefi et al. 2012), power 80%, α = 0.05, and β = 20%. The following sampling formula for two-tailed comparison groups was used (Machin, Campbell, Tan & Tan, 2009):

$$\frac{(z/1-\frac{\alpha}{2}+z/\beta)^2*(\sigma 1^2+\sigma 2^2)}{(\mu 1-\mu 2)^2}=$$

$$(1.96+0.85)^{2}$$
 $(4.07^{2}+3.02^{2})/(9.95-7.86)^{2}=90$

Therefore, 45 patients were required for each intervention and control group. The subjects were considered eligible, if they met the following inclusion criteria: willingness to participate in this study, were on hemodialysis at least for six months (it was adjudged that this amount of time would allow for transition and adjustment to the process of hemodialysis), was receiving treatment three times a week, were over 18 years of age, had no history of seizure and hospitalization due to psychiatric disorders, lack of addiction to drugs or alcohol, lack of strabismus and visual problems based on the researcher's physical examination, no consciousness issues, ability to communicate in Farsi, no stressful life events in the last six months such as the death of a family member, and no previous use of EMDR. Also, those patients who were unwilling to continue with the study or experienced any critical physical and psychological conditions would be excluded from the study.

Procedure

Nurse managers in the hemodialysis wards were informed of the study's aim, procedure and inclusion criteria to help with the identification of eligible subjects. A convenience sample of patients undergoing hemodialysis who met the inclusion criteria was identified, with no patient declining to participate. After explaining the aim and method of the study to eligible patients, an informed written consent form was signed by them. There was no remuneration for the subjects. Subjects were allocated to the groups randomly through a system of sealed envelopes, with each envelope noting assignment to a specific group. The sampling process was continued until the required number of subjects was assigned to each group. To avoid selection bias, the primary researcher generated the random allocation sequence and the second researcher enrolled the patients, assigned them to the groups and approached them about participating in the study. A staff nurse in the hemodialysis ward, who was unaware of the subjects' allocation, collected the data. Another person who was not a member of the research team fed data into the computer so that the researchers had no access to the data processing.

The intervention group received EMDR therapy during hemodialysis six times (three times a week over two weeks) within a total four-week period (Shapiro, 2014). It was carried out for 30-

45 minutes in each session by the primary investigator (an experienced EMDR therapist). In the first session, the traumatic scenes of hemodialysis were identified. Next, the most disturbing scene for the patient was selected for desensitization. The aim of this phase was to familiarize the patient with EMDR and its positive and useful effects as a complementary and non-pharmacological therapy in relieving anxiety and depression. This information also helped with patient participation and cooperation with the researcher when performing EMDR. The procedure was conducted according to the Shapiro protocol (Shapiro, 2014) as follows:

- Facing the negative cognitions related to uncomfortable trauma: the patients were requested to describe their own understandings and visualizations of the traumatic event and recall it;
- Mental rehearsal of the positive recognition;
- Active visual attention to the object (finger movement): the finger rapidly was moved with approximately 30 centimeters distance from patient's eyes in the visual field from right to left and vice versa. This included the sweep motion of the hand in the visual field, whilst the patient was visualizing the event successively;
- Stopping the thought or imagination;
- Deep breathing after each session.

The patients in the control group received routine care. The process of the study is shown in figure 1.

Instruments

Data was collected via a) a demographic and medical information form and b) use of the Hospital Anxiety and Depression Scale (HADS).

The demographic and medical information form

The demographic questionnaire included items related to the patients' age, gender, education level, marital status, employment status, living status, history of hospitalization, underlying diseases, and history of hemodialysis.

Hospital Depression and Anxiety Scale (HADS)

The patients' levels of anxiety and depression were assessed using the Farsi version of the Hospital Anxiety and Depression Scale (HADS). The HADS as a reliable and validated tool screened anxiety and depression (Marrie et al., 2018). This self-reporting tool is time efficient

and despite its brevity, it has been shown to compare well with other measures such as the Beck's Depression Inventory-II and other valid tools (Smarr & Keefer, 2011). The Farsi version of the HADS has an appropriate internal consistency for anxiety (r=0.78) and depression (r=0.86) based on the calculation of the Cronbach's alpha coefficient (Montazeri et al. 2003). The HADS has been used in a previous study to measure the severity of anxiety and depression among hemodialysis patients. Also, it is easy to use and has general acceptability (Zhang, et al. 2014). The basis of working with the above scale requires the patient's own evaluation and self-report of mental anxiety and depression. The tool is consisted of 14 items including two subscales of anxiety (HADS-A) and depression (HADS-D). Each subscale contains 7 items (anxiety items: 1, 3, 5, 7, 9, 11 and 13; depression items: 2, 4, 6, 8, 10, 12 and 14). The anxiety and depression subscales have a 4-point Likert scale from 0 (absence of symptoms) to 3 (the maximal presentation of symptoms), with a total score of 21. The scores are categorized as normal (0-7), borderline (8-10) and abnormal (11-21) (Zigmond & Snaith, 1983). Therefore, a higher score indicates a higher level of anxiety or depression. Scores 11 or above on the anxiety or depression subscales indicate the probability of either anxiety or depression disorders.

Data collection

Baseline data was collected before the EMDR intervention and at the end of the second week. They were monitored closely for the occurrence of possible adverse effects during the intervention.

Ethical considerations

An ethical approval was obtained from the review board affiliated with Shahed University (decree code: 41-228111) before the study. In addition, the research protocol was registered in the Iranian Registry of Clinical Trials (code: IRCT201512 027529N8). Permissions were also obtained from the administrators of the hemodialysis wards. Potential subjects were given explanations about the purpose of the study and the EMDR intervention. They were informed that they could withdraw from the study at any time before the completion of the intervention without any effect on their care. Those patients who agreed to take part in this study were asked to sign the written informed consent form. The anonymity of the patients were ensured using code numbers instead of names.

Data analysis

Using the SPSS software v.21 (SPSS Inc., Chicago, IL) descriptive and inferential statistics were extracted to assess the impact of the intervention on anxiety and depression levels. The data was explored and assessed for missing values, outliers, extreme values and normal distributions. Descriptive statistics with the mean and standard deviation (SD) for continuous variables and frequency for categorical variables were used for the analysis of baseline data.

Two tailed independent samples t-test, Chi-square and Fisher's exact tests were used to assess whether there were any significant differences between patients' characteristics, anxiety, and depression as recorded using the HADS. The level of statistical significance was considered P<0.05.

RESULTS

All 90 subjects fully participated throughout the study process.

The demographic characteristics of the patients

The mean age of the subjects was 51.52 ± 11.134 years, with an age range of 19-70 years. The majority of patients (52.2%) were male and the most prevalent comorbidities were hypertension (66.7%) and diabetes (56.7%). No statistically significant differences were reported in the baseline data between the groups (p>0.05). The baseline characteristics of the patients were reported in Table 1.

The HADS

No statistically significant differences were identified in depression and anxiety levels between the groups at the baseline (p>0.05). The level of anxiety was significantly lower in the intervention group after the EMDR intervention (p<0.05). Similarly, the patients' level of depression was significantly lower in the intervention group after receiving the intervention (p<0.05) (Tables 2, 3).

DISCUSSION

This study investigated the effect of the EMDR intervention on anxiety and depression levels among patients undergoing hemodialysis. Results from this study supported the effectiveness of the EMDR therapy in decreasing anxiety and depression. The reduction of anxiety and depression levels in this study was consistent with the reported positive effect of EMDR therapy in the treatment of patients with various healthcare conditions and suffering from depression and

anxiety as reported by Behnam Moghaddam et al. (2015), Gauhar, (2016), and Marofi et al. (2016).

Anxiety measure in the intervention group was reported as 12.27 ± 3.96 prior to the intervention. After the intervention, it showed an improvement and was reported as 7.27 ± 2.84 . This compares unfavorably with the control group's measure of 10.69 after the intervention period. Cohen et al., (2016) have argued that identifying and treating anxiety in hemodialysis patients can reduce irrational behaviors, conflicts with healthcare staff, and a behavioral noncompliance. While this study did not record any such patient behavior during this study, it is an area that is worthy of increased recognition by other researchers in future studies. Patients deserve the consideration of anxiety when noncompliance becomes a clinical concern. Anxiety relief, the improvement of patients QoL and treatment satisfaction also help with the reduction of the potential for the physiological effects of anxiety on the body (Shirazian et al., 2017). A reduction of the indices of depression (10.87 \pm 3.32 reduced to 6.27 \pm 2.10) in the intervention group showed a marked difference from the control group (11.33 \pm 3.14 after the intervention period) indicating the effectiveness of the intervention. Jhee et al., (2017) noted that the incidence of suicidal ideation as a consequence of depression was reported in 22% of patients undergoing hemodialysis. The psychological stress of ESRD and hemodialysis contribute to depression in this patient group as compared to the general population (Grigoriou et al., 2015) and our results supported this contention.

The EMDR therapy was offered only six times, that was in line with accepted practice. Despite such relatively short intervention time frames compared to other standard psychological interventions such as CBT, a positive outcome was reported. Similarly, Shapiro (2014) reported that the EMDR therapy caused a rapid reduction of negative emotions and disruptive experiences among patients after a limited number of sessions. Therefore, EMDR decreases symptoms significantly faster than standard behavioral and cognitive techniques and fewer sessions are required to show its effect. The use of EMDR can help prevent the requirement to use pharmacological interventions in this groups of patients with a compromised renal function. Given the therapeutic effects of EMDR in reducing depression, it is recommended that this method is used to relieve anxiety and depression in patients suffering from other types of chronic diseases.

The identification of depression and anxiety in patients was made easier by the use of the HADS questionnaire. According to Cohen et al., (2016), depression and anxiety are often undiagnosed in hemodialysis patients and symptoms can be mistaken for those of the renal impairment and/or the effects of hemodialysis (Picariello et al., 2017). The HADS can be used as a screening tool in this patient group given its ease of use and accessibility, and can be administered by clinical nurses as part of their routine patient assessment in hemodialysis wards.

This was a small scale study and due to the nature of EMDR, the patients could not become blind to the intervention. A larger study is needed to compare and contrast other data collection instruments used to measure anxiety and depression. Nevertheless, validity and reliability of the HADS was supported in this study. Despite the small sample size and lack of stratification of patients, it was the first randomized controlled trial that used the EMDR intervention to relieve anxiety and depression among patients undergoing hemodialysis.

IMPLICATIONS FOR NURSING PRACTICE

EMDR as a simple and easy to implement therapy can be educated to clinical nurses to be used for the promotion of patients' psychological wellbeing. It can help with the reduction of the potential for side effects from pharmacological methods used for reliving patients' anxiety and depression. It can help alleviate the negative physical and psychological effects of anxiety and depression on ESRD patients on maintenance hemodialysis, improve their QoL, reduce hospital readmissions, decrease healthcare costs and accelerate patients' discharge from hospital. The authors hope that this research initiates a further use of EMDR therapy by nurses to help patients suffering from the common and debilitating disorder of renal failure. Anxiety and depression are often unrecognized in hemodialysis patients as symptoms can mimic the effects of ESRD coupled with the effects of hemodialysis. Nurses can use the HADS tool and help with the recognition of anxiety and depression in hemodialysis patients. Future studies should be conducted with a larger sample size and with longer follow up periods to assess the long-term effects of the EMDR intervention on patients' anxiety and depression. In addition, a comparison of other non-pharmacological interventions with EMDR is suggested.

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Conflict of interest

The authors have no conflict of interest to declare.

Author contributions

All authors agreed on the final version and met at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]: substantial contributions to conception and design, acquisition of data or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content.

Ethical approval

Shahed University Review Board, No. P/A/16-29

Study registry number

Iranian Registry of Clinical Trials (IRCT) approval: IRCT20152137529N10

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Table 1. Demographic characteristics of the subjects (n = 90)

Characteristic	Total (n = 90) %(n)	Intervention (n = 45) %(n)	Control (n = 45) %(n)	Statistical analysis (independent t- test and Chi- square test), p-value
Age (year)				t=-1.65
	51.52±11.134	49.27±13.23	53.38±10.17	p=0.10
Gender				Fisher's exact
Female	47(52.2)	26(55.3)	21(44.7)	df=1
Male	43(47.8)	19(44.2)	24(55.8)	p=0.390
Education level				
Lower than diploma	50(55.6)	21(46.7)	29(64.4)	Fisher's exact
Diploma and higher	40(44.4)	24(53.3)	16(35.7)	p=0. 130
Marital status				
Single	12(13.3)	7(15.6)	5(11.1)	$X^2=0.73$
Married	68(75.6)	34(75.6)	34(75.6)	df=2
Widow	10(11.1)	4(8.8)	6(13.3)	p=0.690
Employment status				
Unemployed	15(16.7)	9(20.0)	6(13.3)	$X^2=4.96$
Employed	21(21.9)	14(31.1)	7(15.6)	df=3
Retired	19(38.9)	7(15.6)	12(26.7)	p=0.170
Housewife	35(38.9)	15(33.3)	20(44.4)	
Duration of hemodialysis ($M \pm SD$)				
1-5	71(78.9)	36(50.7)	35(49.3)	$X^2=4.39$
5-10	9(10.0)	2(22.2)	7(77.8)	df=2
>10 year	10(11.1)	7(70.0)	30(30.0)	p=0.110

Table 2. The effect of EMDR on the level of anxiety (n = 90)

Before the intervention

(Qualitative)	Group		Total	Statistical analysis,
	Intervention	Control	Total	<i>p</i> -value
Normal (Score 0-7)	-	-		
Borderline (Score 8-10)	19(21.1%)	24(26.7%)	43(47.8%)	Fisher's exact P=0.39
Abnormal (Score of 11-21)	26(28.9%)	21(23.3%)	47(52.2%)	
(Quantitative)	12.27±3.96	11.07±2.84		Independent t-test t=-1.65,df=79.88,P=0.10
After the intervention				
Normal (Score 0-7)	23(25.5%)	6(6.7%)	29(32.2%)	Chi-square test X2(2) =19.07, p=0.01. Cramer's V=r=0.46 Cohen's d=1.03 Effect sizes=large
Borderline (Score 8-10)	17(18.9%)	19(21.1%)	36(40%)	
Abnormal (Score 11-21)	5(5.6%)	20(22.2%)	25(27.8%)	
(Quantitative)	7.27±2.84	10.69±3.24		Independent t-test t=-5.32, df=88, P=0.001 Cohen's d=1.12 Effect sizes=large

Table 3. The effect of EMDR on the level of depression (n = 90)

Before the intervention

(Orralitations)	Group		TD 4 1	Statistical analysis,
(Qualitative)	Intervention	Control	Total	<i>p</i> -value
Normal (Score 0-7)	-	-	-	
Borderline (Score 8-10)	29(32.2%)	22(24.4%)	51(56.7%)	Fisher's exact P=0.20
Abnormal (Score 11-21)	16(17.8%)	23(25.6%)	39(43.3%)	
(Quantitative)	10.78±3.32	11.73±3.05		Independent t-test t=1.42,df=88,P=0.15
After the intervention				
Normal (Score 0-7)	20(22.2%)	5(5.6%)	25(27.8%)	
Borderline (Score 8-10)	13(14.4%)	13(14.4%)	26(28.8%)	Chi-square test X2(2) =14.76, p=0.01. Cramer's V=r=0.40 Cohen's d=0.88 Effect sizes=large
Abnormal (Score 11-21)	12(13.3%)	27(30%)	39(43.3%)	
(Quantitative)	6.27±2.10	11.33±3.14		Independent t-test t=8.99, df=76.87, P=0.001 Cohen's d=1.89 Effect sizes=large

Assessed for eligibility (n=90) Obtaining consent **Enrollment** Excluded (n=0) Not meeting inclusion criteria (n=0) Randomized (n=90) Allocation Allocated to intervention (n= 45) Allocated to control (n= 45) ◆ Received allocated intervention (n= 45) Received allocated intervention (n= 45) • Did not receive allocated intervention (give • Did not receive allocated intervention (give reasons) (n= 0) reasons) (n=0) Follow-Up Lost to follow-up (give reasons) (n=0) Lost to follow-up (give reasons) (n=0) Discontinued intervention (give reasons) (n= 0) Discontinued intervention (give reasons) (n= 0) **Analysis** Analysed (n=45) Analysed (n=45) ◆ Excluded from analysis (give reasons) (n=0) ◆ Excluded from analysis (give reasons) (n=0)

Figure 1. The process of the study according to the Consort flow diagram (2010)