Title: Comparison of the Effects of Emotionally Focused Therapy and Transcranial Direct Current Stimulation on Anxiety and Quality of Life of Patients with Coronary Artery Disease during COVID-19 Pandemic: A Randomized Clinical Trial

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Abstract

Background: The COVID-19 pandemic has increased psychological distress and impacted diagnosis and treatment of noncommunicable diseases. This study aimed to examine the comparative effectiveness of Emotionally Focused Therapy (EFT) and Transcranial Direct Current Stimulation (tDCS) on anxiety and quality of life in patients with coronary artery disease (CAD) during COVID-19 pandemic.

Methods: A total of forty-five participants who met criteria for a current episode of CAD, referred to Shahid-Rajaee Heart Hospital in Tehran, were chosen by convenience sampling method and they were randomly assigned to a 9-week/60-min EFT (n = 15) group therapy, 5-week/20-min tDCS (n = 15) experimental group and one control group (n=15). They were assessed at pre-treatment, post-group, and 3-month follow-up. The study subjects completed the self-reported reliable and valid Persian version of questionnaires, Beck Anxiety Inventory (BAI) and Health-Related Quality of Life (HRQOL). Then, repeated measures analysis of variance, ANOVA, was used to measure inferential statistics.

Results: There were significant improvements in Anxiety and Quality of Life scores in both EFT and tDCS groups over the post and follow-up period ($p \leq 0.01$). However, difference was found when EFT had a greater effect on Anxiety and Quality of Life.

Conclusions: These results showed EFT and tDCS have effective interventions in reducing anxiety and improving the quality of life of CAD patients, but improvements with EFT were greater than those with tDCS.

Key words: Emotionally focused therapy, Transcranial direct current stimulation, Anxiety, Quality of life, Coronary artery disease, COVID-19

Introduction

COVID- 19 is a worldwide crisis with a great impact in health structures which cardiovascular complications, especially acute coronary syndromes, are effective factors in the mortality rate of COVID-19 subjects (Kermani-Alghoraishi, 2021). The resulting deaths of coronary artery disease (CAD) by year 2030 will reach about 23.6 million people which majority will be from South Asia (Saha et al., 2021).

In coronary syndrome , the manifestations of which are physical-psychological, in addition to pain and vomiting, patients suffer from stress (Li et al., 2020) and psychological injuries (Shao et al., 2020) like anxiety (Mirbolouk et al., 2020). Anxiety is functionally related to actual confrontation with danger, not simply the detection of and preparation for danger (Chorpita & Barlow, 1998), which can lead to many serious consequences (Chen et al., 2019), and may affect the quality of life of these patients (Tang et al., 2021).

Considerable agreement exists that quality of life is multidimensional. Coverage may be categorized within five dimensions: physical wellbeing, material wellbeing, social wellbeing, emotional wellbeing, and development and activity (Felce & Perry, 1995). According to a study by Drewes et al. (2021), Coronary heart disease patients experience lower levels of health-related quality of life due to physical and psychological problems.

Depending on the problems of CAD patients, various interventions have been used to improve their problems, but what has not been addressed in previous research is emotionally focused therapy (EFT) and transcranial direct current stimulation (tDCS). EFT is a combination of systemic, humanistic, and attachment theory perspectives (Zwack & Greenberg, 2020). Strengthening of emotional, interpersonal bonds, which is the primary focus of all forms of EFT, can help restore emotional balance, thereby protecting people from chronic feelings of isolation

and the host of health problems that they can cause (Greenman & Johnson, 2022). Reinitz (2018) in a systematic review claimed that EFT may be an effective treatment for couples suffering from symptoms of anxiety and depression.

Also tDCS is a non-invasive brain stimulation technique increasingly used to modulate neural activity in the living brain (Fonteneau et al., 2019) which was first introduced in animal and human experiments in the 1950s, and added to the standard arsenal of methods to alter brain physiology as well as psychological, motor, and behavioral processes and clinical symptoms in neurological and psychiatric diseases about 20 years ago (Stagg et al., 2018). According to research results, tDCS can improve anxiety (de Oliveira et al., 2019). Given the above, no research has compared the effectiveness of EFT and tDCS on health-related anxiety and quality of life in CAD patients. While both methods have advantages, it is questionable which treatment is more effective in reducing the psychological and emotional problems of CAD patients. Is it effective in Covid-19 pandemic or not?

Materials and Methods

Sample

The present study was an applied in terms of purpose and quasi-experimental in terms of research method with pre-test and post-test design with control group with a follow up of 3 months. The statistical population of this study was all patients with CAD referred to Shahid Rajaee Heart Hospital in Tehran in 1398. By available voluntary sampling (non-random selection and random replacement) of 45 patients with CAD based on inclusion and exclusion criteria (inclusion criteria in the research include: 1. Conscious consent to participate in the study, 2. age range between 35

to 70 years, exclusion criteria include: 1. Having history of psychological illnesses (examination through medical records), 2. use of psychiatric and psychotropic drugs, 3. absence from more than two sessions in therapeutic sessions, 4. drug abuse and smoking) were selected and divided into two experimental groups and one control group (15 patients in the EFT group, 15 patients in the tDCS group and 15 patients in the control group).

Since in a similar study, the number of 15 subjects has been suggested to be appropriate (Sarmad et al., 2004), in this study the number of 15 people were selected and assigned to each research group. The EFT group was received 9 sessions of 60 minutes and the tDCS group was received 5 sessions of 20 minutes. In this study, no dropout occurred in any of the experimental and control groups and the number of people in each group remained constant until the end of the study.

Psychometric instruments

Anxiety: the Beck Anxiety Inventory (BAI)

The BAI is a single-factor, non-subscale list of 21 questions. The response indicates how much they have been bothered by each symptom over the past week. It was developed as a measure adept at discriminating between anxiety and depression (Beck & Steer, 1990). The grading method is done in a 4-point Likert scale (0 to 3). In Iran, the internal consistency reliability (Cronbach's $\alpha = 0.92$) and validity ($r = 0.83$, $p < 0.001$) of the Persian version of BAI were confirmed (Kaviani & Mousavi, 2008).

MacNew Heart Disease HRQOL questionnaire

MacNew's Health-Related Quality of Life Questionnaire has 27 questions that measure the three components of physical function, emotional function, and social function. Fourteen questions are about physical functioning, 14 questions are about emotional functioning, and 13 questions are about social functioning, and quality of life of cardiac patients. The time frame for the MacNew is the previous two weeks. The questionnaire is graded on a 7-point Likert scale from 1 to 7. Convergent and divergent validity of the Persian version of MacNew was confirmed and internal consistency reliability (Cronbach's $\alpha = 0.94$) was calculated by Abbasi et al. (2017).

Emotionally Focused Therapy

In this study, there are 9 sessions of EFT based on Johnson and Greenberg theory and Bowlby (1969) attachment theory that people in the experimental group were trained. The validity of these sessions has been confirmed in the research of Johnson (2008) and Johnson (2012).

During sessions 1 to 3, the facilitators familiarized the participants with the objective of the intervention. They explained the general rules of treatment, introduced the principles of EFT and performed the pretest. Unrecognized emotions that underlie interactive situations were identified. They focused more on the needs, emotion and fears of attachment. The experiences, attachment, needs and desires of participants were validated. Focused on the secondary emotions that are revealed in the interactive cycle, and explored them to identify basic and unknown emotions. Initial emotions were discussed and processed, and awareness of primary emotions and hot cognitions of participants were raised.

During the fourth to sixth sessions the facilitators re-stated problems in terms of underlying feelings and needs of attachment. They emphasized participants'

ability to express emotions, explained the impact of fear and its defense mechanisms on cognitive and emotional processes, described the cycle in the context and field of attachment. The subjects were encouraged to identify rejected needs and aspects of self-denial, to draw their attention to how they interact with each other, to express attachment needs and also to identify denied needs and increase acceptance of corrective experience. Facilitators informed participants about underlying emotions and revealing each person's position in the relationship. They emphasized the acceptance of the individual's experiences and new ways of interacting, highlighting and re-describing attachment needs, and pointing to their health and naturalness.

Sessions 7 to 9 involved developing needs, and desires. The expectations and early emotional experiences were expressed and internal needs and relationships were recognized. Facilitators tried to create new attachments with secure bonds. Interactive situations between people were created, tried to end old interactive patterns. Attachment needs were clarified and recalled. The changes that have taken place during treatment were strengthened. The differences between current and old interactions were highlighted. A relationship based on a secure link was formed so that discussed problems and searched solutions do not harm them. Changes were evaluated, and facilitators implemented posttest.

Transcranial Direct Current Stimulation

The tDCS protocol basically followed the method reported by (Loo et al., 2010) and was given three times per week (Monday, Wednesday, Friday) 9:0 in the morning. The 15 subjects were treated using a continuous current electric stimulator (Caputron Activa Dose II, Gilroy, USA). The montage was bifrontal with the anode over F3 (left dorsolateral PFC) and the cathode over F4 (right dorsolateral PFC) according to the international 10/20 EEG system. Conductive rubber electrodes (7×5 cm=35 cm^2) were placed in saline-soaked surface sponges. The amount of saline per sponge

was standardized (15–20 ml per sponge). After careful skin cleaning, electrodes were secured in position with an elastic tubular netting. A conductive electrolyte gel was used between the electrode and the skin. Stimulation was given at 1 mA for 20 min for five treatment sessions.

At the end of the last session, subjects answered Beck's anxiety test and health-related quality of life questionnaire.

Data analysis

The data obtained from the questionnaires were analyzed using SPSS software (version 24; IBM Corp., Armonk, NY, USA) in two descriptive and inferential sections (repeated measures analysis of variance, ANOVA).

Results

Demographic information and descriptive statistics, including frequency, and mean and standard deviation, are reported in this section. The mean age in the EFT group was 55.40, the standard deviation was 10.43, in tDCS group the mean was 50.42, the standard deviation was 9.27, and in the control group the mean was 55.07 and the standard deviation was 10.38. Also, among the sample members in the experimental group, 53.3% were male and 46.7% female, and in the group of tDCS 42.9% were male and 57.1% were female. In Table 1, the mean and standard deviation of the study groups in pre-test, post-test and follow-up are presented separately.

Table 1

Table 2

Table 3

Discussion and conclusion

The aim of this study was to compare the effectiveness of EFT and tDCS on anxiety and quality of life of patients with CAD. According to the results of Table 2, which showed the effectiveness of EFT and tDCS on anxiety, it can be concluded that one way to reduce anxiety is to use EFT throughout the lives of these patients, and in addition, they can benefit from tDCS. Also, according to the results of Table 3, which shows the effectiveness of EFT and tDCS on quality of life, it is necessary to benefit from these two treatments for the greater well-being of patients and creating favorable conditions for patients with heart disease.

In general, anxiety is high in patients with heart disease (Meyer et al., 2019; Ryan, 2020a). Regarding the effectiveness of psychological interventions and treatment of tDCS in reducing anxiety syndrome, the results of the present study are consistent with the study of Naeim et al. (2021) and Ski et al. (2019) In addition, the effectiveness of EFT compared to other therapies is consistent with the results of a meta-analysis by Rathgeber et al. (2019). New concepts and ways of understanding emotion help us work with it more effectively, and many of these new ways offer an exquisite fit with EFT interventions to demonstrate less neural reactivity to rejection situations and suffer less from severe anxiety and depression (Johnson, 2019). Chen et al. (2021) also showed that because of the high frequency of anxiety and depression after percutaneous coronary intervention in patients with CAD and its effect on performance and treatment, the recovery requires special attention to this issue and efforts to Investigating effective and appropriate factors and strategies to reduce it.

Explaining the results, emotionally focused group therapy gives patients the ability to control negative emotions such as anxiety and increase their psychological adjustment by increasing

emotional awareness. Emotion group therapy methods try to encourage patients to question their disturbing thoughts during treatment and examine alternative self-talk to deal with these emotions and rumination that cause physical and mental disturbance (Judd, 2016). Also, according to emotionally focused group therapy, patients' disturbances are caused and continue by pervasive states of negative emotion and attachment disorders, disregard for inner needs and desires, negative interaction patterns, and inappropriate emotional experience. In fact, emotionally focused group therapy tries to identify emotions and turn them into understandable and constructive messages. Emotional skills, defined as the ability to recognize and express emotions, as well as the ability to empathize with others, reduce anxiety and increase feelings of security, reduce uncriticism in patients, and are essential in maintaining and maintaining interpersonal communication (Greenberg et al., 2003). EFT as a process-oriented psychotherapy, is an ideal approach to working with relationships during the global pandemic helping to solidify an "in it together" approach required to survive the pandemic (Allan et al., 2021).

Also, the results showed that EFT and tDCS are effective in improving the quality of life, and each of them individually was able to improve the quality of life in patients with heart disease. In addition, EFT was more effective in improving quality of life than tDCS. Quality of life is an important factor in patients with CAD so that there is a relationship between physical inactivity and quality of life in patients with CAD. Thus, physical inactivity can explain the physical weakness and quality of life associated with the health of these patients, which in turn worsens the psychological symptoms in heart patients (Ryan, 2020b; Wardoku et al., 2019). The treatment of tDCS through the blood supply of sedentary patients seems to provide the basis for their mobility (Miuli et al., 2020) and this mobility in heart patients can provide the basis for improving the quality of life so that the results Showed tDCS to improve quality of life. Each of the treatment approaches,

from a specific point of view, has considered individuals and addressed the issue of adaptation and quality of life. Among these, EFT integrates experiential and systemic perspectives. People are viewed as constructive, self-organizing beings having inherent tendencies to survive and grow (Greenberg & Johnson, 1988). Johnson et al. (1999) mentioned four key assumptions of EFT: First, emotional responses and interactional patterns are reciprocally determining and both must be addressed in therapy. Second, partners are stuck in negative patterns that preclude the responsiveness necessary for secure bonding. They are not viewed as immature or unskilled but, rather, as needing support to formulate their attachment needs and fears in a manner that promotes secure bonding. Third, emotion is seen as a key element in the definition and the redefinition of close relationships. New emotional experience and new interactions are necessary for change to occur. Fourth, adult intimacy is best viewed as an attachment process.

The result of a research by Kazemi Rezaei et al. (2019) showed that emotion regulation training, helps individuals manage their conflicting emotions by making them aware of feeling and how to properly use of cognitive emotion regulation strategies and provides the basis for how emotions can be managed appropriately to improve the quality of life of patients with Cardiovascular diseases.

Although in this study, in order to control the interfering variables and possible biases, individuals were randomly divided into two experimental groups and a control group but the lack of research related to the subject, especially in the country, was one of the limitations of this research in terms of discussing the findings. Also, the use of self-report questionnaires was another limitation of the present study. Therefore, it is suggested that due to the characteristics of patients with CAD, such as anxiety and behavioral disorders and reduced quality of life in special cases,

more attention should be paid to the use of EFT. It is also suggested that in future studies, this study be tested in various hemodialysis centers across the country.

Abbreviations

BAI: Beck anxiety inventory; CAD: Coronary artery disease; EFT: Emotionally focused therapy; HRQOL: Health-related quality of life; tDCS: Transcranial direct current stimulation.

Declarations

Ethics approval and consent to participate

It should be noted that the present study was approved by National Ethics Committee for Biomedical Research with the code ID: IR.IAU.NAJAFABAD.REC.1398.088 in 05/09/2019 and the privacy and confidentiality of the collected data was observed. All participants gave their informed consent prior to their inclusion in the study. The control group was also trained to observe the ethical standards of EFT and tDCS.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author Contributions

SG developed the main idea and carried out the experiment. SE wrote the manuscript with support from SG. SG and SE analyzed data and assessing scales. Both of the authors read and approved the final manuscript.

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Conflict of interests

The authors declare that they have no conflict of interest.

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Table 1. Mean and standard deviation of research variables in pre-test, post-test and follow-up

Pre-test				Post-test		Follow-up	
Research variables	Group	Mean	SD	Mean	SD	Mean	SD
Anxiety	Control	۲۹/۹۲	۴/۲۳	۳۰/۰	۴/۸۳	۳۱/۶۴	۶/۱۷
	Experimental (EFT)	۲۹/۷۳	۴/۵۲	۱۰/۲۰	۵/۳۰	۱۱/۷۳	۴/۵۴
	Experimental (tDCS)	۲۹/۰۷	۷/۱۸	۱۶/۵۷	۵/۴۰	۱۷/۰	۴/۹۷
Quality of life	Control	۱۱۶/۲۱	۳۴/۱۴	۱۱۵/۷۱	۳۲/۶۵	۱۱۴/۷۸	۳۱/۹۹
	Experimental (EFT)	۱۳۴/۰	۱۲/۶۳	۸۰/۴۰	۱۵/۹۳	۷۹/۶۰	۱۰/۶۰
	Experimental (tDCS)	۱۳۱/۸۵	۱۳/۷۳	۹۵/۱۴	۱۳/۳۸	۹۵/۹۲	۱۲/۶۷

Table 2. Results of repeated measures analysis of variance for within-group effects and interaction

Within Subjects Effect		SS	df	MS	F	P	Eta squared	Test power
Anxiety	Greenhouse-Geisser	۳۷۲/۳۱	۱/۶۷	۲۲۳/۰۳	۱۰/۷۲	۰/۰۰۰۱	۰/۲۹	۰/۹۷
Anxiety and group	Greenhouse-Geisser	۵۲۳/۱۷	۱/۶۷	۳۱۳/۴۱	۱۵/۰۶	۰/۰۰۰۱	۰/۳۷	۰/۹۹

Table 3. Results of repeated measures analysis of variance for within-group effects and interaction

Within Subjects Effect		SS	df	MS	F	P	Eta squared	Test power
Quality of life	Sphericity assumed	۳۷۳۵۱/۳۶	۲	۱۸۶۷۵/۶۸	۱۵۵/۰۰	۰/۰۰۰۱	۰/۸۶	1
Quality of life and group	Sphericity assumed	۱۳۲۹/۹۳	2	۶۶۴/۹۶	۵/۵۲	۰/۰۰۷	۰/۱۷	۰/۸۳