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Investigating the Effectiveness of Process-Based Therapy in Anxiety in Women Suffering from Iron Deficiency Anemia: A Single-Subject Study

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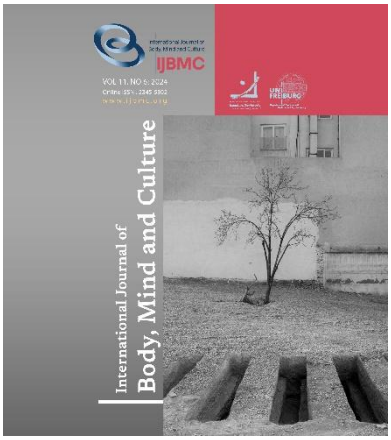

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ABSTRACT

Objective: Due to menstruation, pregnancy, and poor iron intake and absorption, women are prone to iron deficiency anemia. The objective of this study was to investigate the effectiveness of process-based therapy in anxiety in women suffering from iron deficiency anemia and generalized anxiety disorder.

Methods and Materials: This study followed a single-subject experimental design. Six female participants suffering from iron deficiency anemia were selected through a purposive sampling method; they received process-based therapy during nine 60-minute sessions. In the pretest phase, the participants filled out the Generalized Anxiety Disorder questionnaire (Newman, Zueling, Kachin & Constantino, 2002; fourth edition) and were interviewed. They also filled out Beck's (1988) Anxiety inventory in the baseline and follow-up phases. The data were analyzed through visual analysis, stability index, and recovery percentage formula.

Findings: The results showed that the total percentages of anxiety reduction were 56.21% and 75.5% in the intervention and follow-up phases, respectively. They indicated the success of the therapy.

Conclusion: Process-based therapy reduced anxiety in women suffering from anemia with generalized anxiety disorder. Psychologists and researchers can apply the results of the present study.

Keywords: process-based therapy; anxiety; women; anemia; generalized anxiety.

Introduction

As members of society, women have various essential responsibilities that contribute to the growth and development of the family and society. Due to menstruation, pregnancy, and poor iron intake and absorption, they are vulnerable to iron deficiency anemia and its side effects (Kassebaum, 2016; Kassebaum et al., 2014). Anemia can be associated with a variety of serious health problems, such as severe fatigue, weakness, neurological disorders, and cardiovascular diseases (Kassebaum et al., 2014). Anemia is a multifactorial condition that is defined as an abnormally low number of red blood cells or low hemoglobin level; iron deficiency anemia is highly prevalent in women and preschool children, regardless of Geographical region and

economic status (Kassebaum, 2016; Vulser et al., 2016). Moreover, the female gender is mentioned as one of the independent risk factors of psychiatric disorders in individuals with iron deficiency (Zamani et al., 2022). According to the data of a Persian national cohort study (prospective epidemiological study) on chronic non-communicable diseases, the prevalence of anemia in Iranian women is significantly higher than that of men. The prevalence of anemia in all age groups of women (12.5%) is considerably higher than in men (4.5%). Iron deficiency anemia is mainly caused by menstruation or pregnancy (Vanishri et al., 2017).

Research has shown that iron deficiency is associated with anxiety, and there is a high correlation between iron deficiency anemia and generalized anxiety disorder in women (Chen et al., 2013; Kassebaum, 2016; Kassebaum et al., 2014). Generalized anxiety disorder, as one of the common psychiatric disorders, is a chronic anxiety disorder that is characterized explicitly by extreme and persistent feelings of anxiety. In this disorder, anxiety refers to all events of daily life and is characterized by physical symptoms of restlessness, fatigue, muscle tension, irritability, problems in concentration, and insomnia (Bahodirovna et al., 2023; Bakhtiyarovich et al., 2023; Fernandez-Jimenez et al., 2020; Sauletzhanovna et al., 2024; Savarese, 2022). Most scientific studies on the epidemiology of mental disorders in Iran have concluded that generalized anxiety disorder is the most common anxiety disorder and has a high correlation with other disorders (Mohammadi et al., 2005).

One of the interventions that can effectively reduce the psychological complications of iron deficiency is Process-Based Therapy (PBT); it is a new model of evidence-based treatment that includes identifying and addressing the main change processes while focusing on the client's concerns. Process-based therapy emphasizes function over content, based on identifying and testing key change processes to provide the best treatment to an individual in a specific context at a particular time. Process-based therapy is one of the change processes that can be used for a wide range of individual problems in a completely personalized way (Hofmann & Hayes, 2019; Hofmann et al., 2021). By focusing on a client's most important biological, psychological, and social processes, therapists and researchers focus more on procedures and methods based on traditions, approaches, goals, and current conditions. They identify the strategies that best lead to therapeutic success (Hayes et al., 2020). The process-based approach allows simultaneous emphasis on the individual, context, and clinical symptoms (Hofmann & Hayes, 2019; Hofmann et al., 2021).

The higher risk of psychiatric disorders in individuals suffering from iron deficiency (Woodman et al., 1999) and insufficient attention to the psychological effects of iron deficiency show that to improve the quality of life of women. More attention should be paid to the non-hematological manifestations of this rare element (Lee et al., 2020). In addition, it is essential to conduct studies focusing on reducing this disease's non-hematological complications and use new effective interventions that save treatment costs, increase individuals' satisfaction with psychological treatments, and consequently increase their willingness to receive psychological services. Therefore, process-based therapy can be essential, free from separate protocols for each disorder and seeking to adjust treatment techniques according to an individual's specific problems and context. On the other hand, as research studies have shown, generalized anxiety disorder has an economic burden on the healthcare system due to more use of professional health services compared to other anxiety disorders (Fernandez-Jimenez et al., 2019), more visits to general practitioners and family doctors (only 14% of clients refer to mental health specialists), and services provided by cardiologists and gastroenterologists (Hunt et al., 2002).

Iron is a required co-factor in regulating dopamine synthesis and the dopamine receptors in the brain. It has been discovered that the levels of iron and ferritin in the cerebrospinal fluid of GAD patients are abnormally low (Earley et al., 2000; Mizuno et al., 2005). It has already been shown that GAD is related to depression and anxiety (Tuncel et al., 2009). In the last few years, many clinic or community-based epidemiologic studies with different scales evaluating the symptoms of depression and anxiety revealed that the depression and anxiety symptoms are higher in the GAD patients than those in the control group (Haji-Adineh et al., 2019; Molavi et al., 2018; Mosko et al., 1989; Picchietti & Winkelman, 2006). The underlying mechanism of the pathophysiological link between anxiety and GAD has not been completely understood, and there were only a few studies on the subject. However, hypofunction in the dopaminergic system has been considered/hypothesized as a common

pathophysiology of both diseases (Allen et al., 2003; Barriere et al., 2005). As a result, the lack of effective psychological and drug treatments and the lack of efficient and effective psychological therapies impose financial and spiritual costs, which can be reduced to some extent through new effective interventions that have positive consequences for all members of society; this is another reason for the significance of conducting this study. Therefore, this research study examined if process-based therapy was effective in reducing the anxiety level of women suffering from iron deficiency anemia and generalized anxiety disorder.

Methods and Materials

Study Design and Participants

This applied study was a part of a single-subject design using clinical trials and multiple baselines. In this type of design, the researcher examines the effect of one variable on another variable considering one or more participants; it is one of the most useful statistical methods to reduce or increase intentional behaviors. The participants participate in the baseline, treatment, post-treatment, and follow-up phases. The statistical population of this study included all women suffering from anemia with generalized anxiety disorder who visited the healthcare centers in Arak during the second six months of 2023. Samples were collected through the purposive sampling method. The inclusion criteria were a definite diagnosis of anemia caused by iron deficiency, simultaneous suffering from generalized anxiety disorder based on the diagnostic interview with a clinical psychologist considering DSM-5 (Diagnostic and Statistical Manual of Mental Disorders), a score of at least 7.5 in Generalized Anxiety Disorder questionnaire, willingness of the client to participate in the study during the treatment, age range of 25 to 35 years (according to the age range of the prevalence of iron deficiency anemia), and the educational level of at least a diploma. In addition, the absence of the following items was taken into account: suffering from a personality disorder based on the diagnostic interview according to DSM-5, having a main or co-occurring disorder, excluding the disorders targeted in this research study, having a history of receiving psychological and pharmacological interventions in the last one year and during this study, having suicide risk, and having the history of substance abuse during the previous one year. Moreover, the exclusion criteria included two sessions of absence during the treatment, non-cooperation in the specified tasks, and unwillingness to continue participating in the research study. It should be noted that participants should not have any history of taking psychiatric medications for generalized anxiety disorder or anemia.

Having referred to the health care center, the researchers received the names and phone numbers of the clients. Then, those who met the study's inclusion criteria were invited to fill out the Generalized Anxiety Disorder questionnaire (GADQ-IV), and a diagnostic interview was conducted with those who scored at least 7.5. Therefore, after considering the inclusion criteria, six individuals were selected to be simultaneously treated through nine process-based sessions in two 60-minute sessions per week. The participants completed Beck's (1988) Anxiety Inventory twice a week during the first two weeks (baseline) and once in the third week; all six participants received the treatment in the third week. In other words, in the third week, the last phase of the baseline (i.e., the fifth) was implemented, and the first treatment session was performed three days later in the same third week.

Moreover, the study instruments were distributed to the participants in sessions three, six, and nine. When the treatment was done, one-month, 1.5-month, and three-month follow-ups were applied to all participants. The treatment protocol used in this study was derived from the process-based approach. As mentioned earlier, this approach is far from unique protocols for each disorder; it focuses on the change processes needed by each individual to achieve better performance. Therefore, personalized treatment was implemented according to each participant's conditions and change processes.

Data Collection Tools

Structured Clinical Interview for DSM-IV (SCID): Structured Clinical Interview for DSM-I is a flexible interview developed by First et al. (1996). Tran and Smith (2004) reported a Kappa coefficient of 60% as the inter-rater reliability coefficient for SCID. Sharifi et al. (2013) conducted this interview with 299 individuals after translating it into Persian; the diagnostic agreement was moderate for most specific and general diagnoses (kappa above 60%). The overall agreement was also appropriate (Kappa for total current diagnoses

was 52%, and for complete lifetime diagnoses was 55%). This instrument was used as a psychological diagnostic assessment (Tran & Smith, 2004).

Generalized Anxiety Disorder Questionnaire-IV (GADQ-IV): This instrument is a valid self-report measure of generalized anxiety disorder, which identifies individuals who meet DSM criteria for the disorder following a comprehensive clinical interview. Recent studies showed that GADQ-IV correctly diagnosed more than 92% of individuals who received a clinical diagnosis of generalized anxiety disorder according to DSM criteria. The items of this questionnaire focus on the presence of excessive and uncontrollable worry, including worrying about repeated non-significant issues for less than six months. Newman et al. (2002) developed a formula to obtain a total score by taking into account responses to all items (from 0 to 12) and a cut-off score (i.e., a score of 7.5) to determine the probable state of the disorder diagnosis through valid preliminary evidence. They reported the mean score of this questionnaire as 2.69 with a standard deviation of 3.14 and a test-retest reliability of 92% in the sample of non-anxious individuals (Newman et al., 2002). Also, according to the research of Naeinian et al. (2011), this scale has good validity and reliability in Iran, as Cronbach's alpha was 0.85 and the retest coefficient was 0.48 (P>0.01) (Naeinian et al., 2011). In the present study, Cronbach's alpha for this scale was also 0.87.

Beck's Anxiety Inventory: This 21-item questionnaire was developed by Beck et al. (1988); each item is scored between 0 and 3. The range of scores is between 0 and 63, where a high score indicates a higher level of anxiety. Beck et al. (1988) reported the internal consistency of this questionnaire as 90% and the test-retest reliability coefficient as 0.75 (Beck et al., 1988). Kaviani and Mousavi (2009) reported the Cronbach's alpha coefficient of this questionnaire as 92%. In the present study, the reliability coefficient of this questionnaire (0.83) was calculated using Cronbach's alpha, considering a sample of 30 normal individuals. This instrument was used in the current research to evaluate the intensity of anxiety during the study (Kaviani & Mousavi, 2009).

Intervention

One researcher presented and managed the sessions in the present study, and an expert statistician conducted the data analysis. Clinical significance (i.e., the scientific value or importance of the effect of the intervention) was used for data analysis.

Data analysis

Two prominent and widely used approaches in clinical significance are the reliable change index and the normative comparison approach. Reliable change index was first introduced by Jacobson and Truax (1991) to analyze data obtained from single-subject designs. In this index, the posttest score is subtracted from the pretest score, and the result is divided by the standard error of the difference between the two scores. In addition, clinical significance was estimated through the total percentage recovery formula, first introduced by Blanchard and Schwarz (1988) to analyze single-subject data. In this index, the posttest score is subtracted from the pretest score, and the result is divided by the standard error of the difference between the two scores. Visual representation (i.e., a graphic diagram) and diagnostic improvement were used to analyze the data and evaluate the efficiency. In addition, the results before and after the intervention were tabulated.

Findings and Results

The demographic characteristics of the participants are presented in Table 1.

Table 1

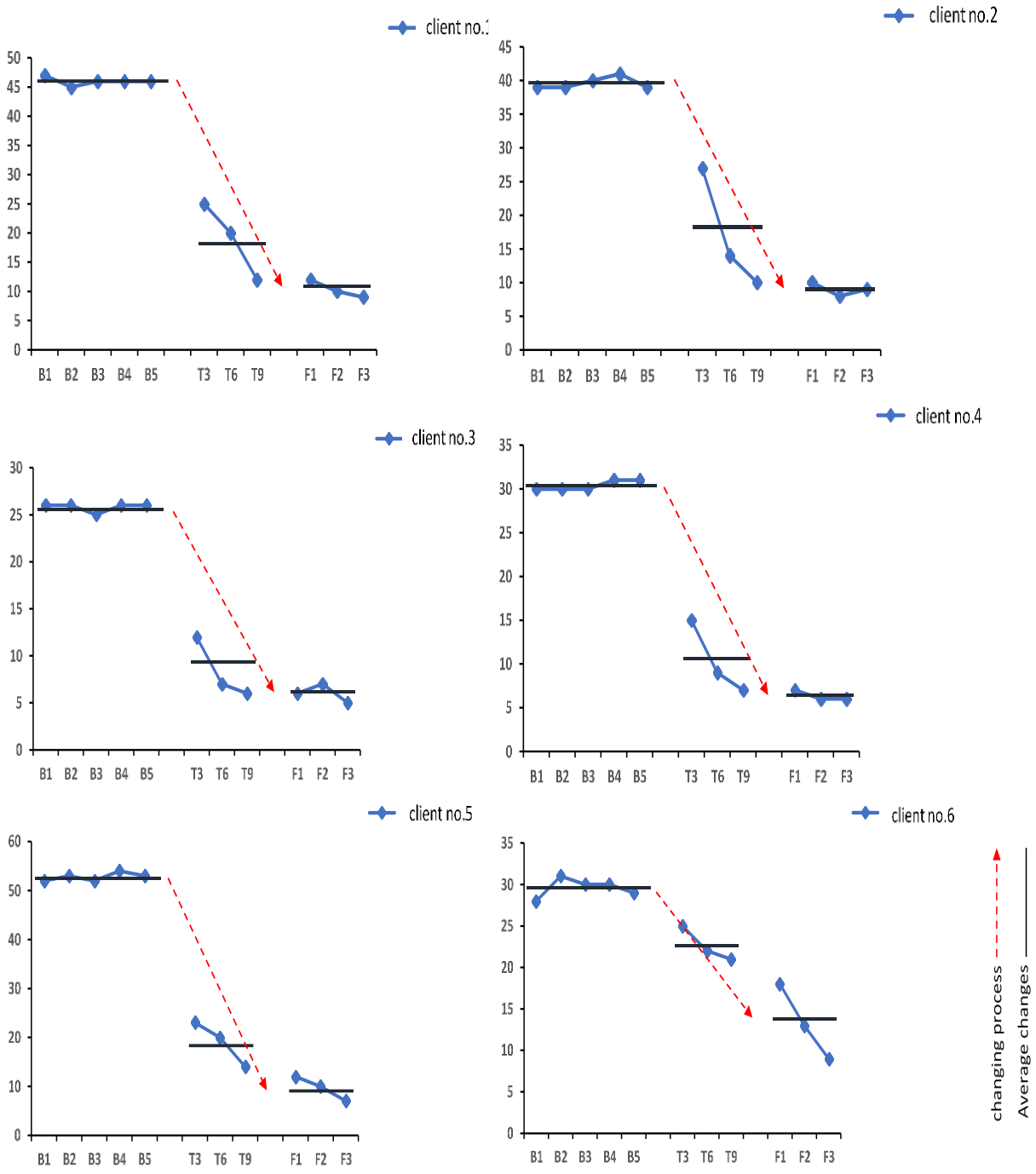
The participants' demographic characteristics

Participants	Age	Level of education	Occupation	Marital status
1	25	Diploma	Housewife	Married
2	34	A.A.	Student	Married
3	25	Diploma	Jobless	Single
4	32	B.A.	Radiologist	Married
5	26	B.A.	Employee	Single
6	33	M.A.	Employee	Married

Moreover, Table 2 represents the data considering all six participants' baseline, treatment, and follow-up phases. All six participants' mean and anxiety scores decreased in the treatment and follow-up phases compared to the baseline:

Figure 1

The change process of anxiety scores of the six participants in the baseline, treatment, and follow-up phases



*B: Baseline T: Treatment F: Follow up

Table 2

Phases investigating the effectiveness of process-based therapy in anxiety level

Treatment processes	The first participant	The second participant	The third participant	The fourth participant	The fifth participant	The sixth participant
Baseline						
The first baseline	47	39	26	30	52	28
The second baseline	45	39	26	30	53	31
The third baseline	46	40	25	30	52	30
The fourth baseline	46	41	26	31	54	30
The fifth baseline	46	39	26	31	53	29
The baseline mean	46	39.6	25.8	30.4	52.8	29.6
Treatment						
The third session	25	27	12	15	23	25
The sixth session	20	14	7	9	20	22
The ninth session	12	10	6	7	14	21
The mean of the treatment session	19	17	8.33	10.33	19	22.67
Stability index	-8.05	-6.74	-5.21	-5.99	-10.08	-2.06
The reduction of anxiety after the treatment (%)	58.59	57.07	67.71	66.01	64.38	23.41
Total reduction of anxiety (%)	56.21					
Follow-up phase						
The first follow-up	12	10	6	7	12	18
The second follow-up	10	8	7	6	10	13
The third follow-up	9	9	5	6	7	9
The mean of follow-up phases	10.33	9	6	6.33	9.67	13.33
Stability index	-10.64	-9.13	-5.91	-7.18	-12.87	-4.84
The reduction of anxiety after the follow-up phase (%)	77.54	82.92	76.74	79.17	81.68	54.96
Total reduction of anxiety (%)	75.50					

According to Table 2, the stability indices at the end of the treatment and the follow-up sessions were -8.05 and -10.64 for the first participant, -6.74 and -9.13 for the second participant, -21.5 and -5.91 for the third participant, -5.99 and -7.18 for the fourth participant, -10.08 and -12.87 for the fifth participant, -2.06 and -4.85 for the sixth participant; according to the stability index formula, they showed the significance of the effect of process-based therapy on anxiety. When this index was higher than Z = 1.96, it confirmed the significance of the statistical results; with 95% confidence (P<0.05), it could be concluded that there was a change that was caused by the intervention (i.e., the change was not accidental).

The anxiety reduction percentages in these six participants after the treatment were 58.69, 57.07, 67.71, 66.01, 64.38, and 23.41, respectively. In addition, the percentages of reduction of anxiety in these six participants after the follow-up sessions were 77.54, 82.92, 76.74, 79.17, 81.68, and 54.96, respectively. They were also significant based on the improvement percentage formula. Thus, based on the stability index and total reduction of anxiety of these six participants in the treatment and follow-up phases, it could be stated that the process-based therapy was effective in reducing the participants' anxiety levels.

Discussion and Conclusion

This study was conducted to examine the effectiveness of process-based therapy in anxiety in women suffering from iron deficiency anemia and generalized anxiety disorder. The results indicated that process-based therapy led to the reduction of anxiety scores. The findings of this study were consistent with prior findings (Faramarzi et al., 2008; Rezaei et al., 2013). These studies considered the role of cognitive (inefficient beliefs), emotional (self-compassion, acceptance, and anxiety sensitivity), and attention (mindfulness, mental rumination, worry, conscious action) as mediating variables in the pathology of anemia and anxiety. As mentioned, process-based therapy is based on interventions considering all evidence-based change processes regardless of a specific therapeutic orientation. Therefore, this treatment method tries to identify incompatible processes that play a crucial role or to connect the target to a significant mediating

variable so that individuals would be aware of these processes.

Then, among the techniques of valid treatment approaches that significantly affect changes in this incompatible process, the most effective ones are used to achieve the therapeutic goal of creating a compatible process. The symptoms of anxiety can be reduced through the effect of the therapeutic technique on the mediating variable. In this vein, the techniques used to change the functioning of negative emotions encourage individuals to focus on how they deal with negative emotions in life. The use of arousal reduction processes is beneficial in most anxiety disorders (Huguet et al., 2014). Since patients with anemia show high vulnerability to anxiety and are ready to misinterpret the physiological symptoms of anxiety, they are informed that they have disastrous and incorrect views about themselves and their ability level, which leads to a negative and selective bias about their efficiency and capability. For instance, an individual with anemia often experiences physiological symptoms of anxiety, such as extreme fatigue and weakness, and thinks that he cannot start a severe task or make daily decisions; this ineffective belief leads to anxiety, depression, and a drop in occupational and social performance. It would be impressive to inform him that these symptoms occur in anemia, and in many cases, they are not a sign of inefficiency. Another effective technique that helps explain the treatment's effectiveness is daily relaxation and mindfulness practice. The participants were trained to use relaxation techniques and mindfulness exercises when the first physiological signs of anxiety appeared. These techniques improved their conditions by reducing the symptoms of anxiety and tension.

The participants were in the age range of 25-35, which reduced the possibility of generalizing the effectiveness of this treatment to younger or older individuals. Second, caution should be exercised while generalizing the results due to the small number of participants. Third, random sampling was impossible due to the criteria for selecting participants. Therefore, it is suggested that researchers replicate this study while examining larger samples in other contexts with the random sampling method. Then, they can compare the results with those of the current research study.

Moreover, the current research only deals with a small part of the problems of several people suffering from anemia. Considering the non-hematological complications of anemia, it is suggested that researchers conduct more applied research on these complications and how to reduce them in women. It is also recommended that the effectiveness of process-based therapy in other psychological problems be investigated. The efficacy of this treatment can also be compared with that of different treatments, such as emotion-based therapy.

The present study showed that the participants realized the self-reinforcing feature of their maladaptive emotional style and became aware of its adverse effects on different aspects of their lives. In addition, they could follow compatible dynamic styles by using self-acceptance and compassion techniques; this reduced their anxiety level. Therefore, this intervention had positive results for all participants and reduced some of the non-hematological complications of iron deficiency anemia. According to the findings of this study and obvious psychological complications in people with anemia, process-based therapy can be used together with medical treatments to treat mental disorders and to improve the overall performance of individuals with anemia.

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Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The study protocol adhered to the principles outlined in the Helsinki Declaration, which provides guidelines for ethical research involving human participants.

Transparency of Data

In accordance with the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

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Authors' Contributions

All authors equally contributed to this study.

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