



The Effectiveness Based on Mindfulness Cognitive Therapy on Internalized Shame, Marital Disaffection and Tendency to Divorce in Unfaithful Couples

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ABSTRACT

Objective: The present study aimed to investigate the effectiveness of mindfulness-based cognitive therapy on internalized shame, marital disaffection, and inclination toward divorce in couples who had experienced infidelity.

Methods: This research was conducted using a quasi-experimental design with pre-test and post-test and a control group. The statistical population of this study consisted of all couples who, due to experiencing infidelity by their spouses, referred to licensed counseling and psychotherapy centers of the Iranian Psychological and Counseling Organization, the State Welfare Organization, or psychiatrists licensed by the Iranian Medical Council (Anis Andisheh Clinic) in District 3 of Tehran, during the first quarter of 2024. In this study, the sample size for each of the experimental groups and the control group was 16 people (8 women and 8 men), and a total of 32 individuals were selected. According to the quasi-experimental design, they were chosen through convenience sampling from among volunteers and then randomly assigned to the experimental and control groups by lottery. Data collection instruments included the Internalized Shame Scale by Cook (1993), the Marital Disaffection Scale by Kaiser (1993), and the Inclination Toward Divorce Scale by Rusbult et al. (1986). In this study, mindfulness-based cognitive therapy consisted of eight weeks of two-hour sessions based on the mindfulness-based cognitive therapy protocol by Crane.

Findings: The results of data analysis indicated that mindfulness-based cognitive therapy had an effect on internalized shame, marital disaffection, and inclination toward divorce in couples who had experienced infidelity.

Conclusion: Considering the results, it can be stated that mindfulness-based cognitive therapy influences the research variables. It is suggested that further studies be conducted in this area to enhance external validity.

Keywords: *Mindfulness-Based Cognitive Therapy, Internalized Shame, Marital Disaffection, Inclination Toward Divorce, Infidelity.*

1. Introduction

Marital infidelity is a prevalent issue that family therapy specialists regularly encounter in clinical settings, often leading to profoundly distressing experiences for those involved. Not only can this issue result in family breakdown, but it is also considered one of the most serious crises in the domain of family relationships. Marital infidelity, which can involve extramarital sexual or emotional relationships outside the accepted framework of marriage, imposes severe emotional consequences on couples. Based on clinical observations and scientific research, the disclosure of marital infidelity can have devastating effects on marital relationships. Individuals affected by infidelity may experience intense anger toward their spouse, internalized shame, depression, feelings of rejection, aggression, vengefulness, apathy, helplessness, victimization, abandonment, shock, dysfunctional thoughts, and even violent behaviors, including homicide (Karami, 2024; Karimzadeh & Abdollahi, 2022).

One of the major consequences of infidelity in family relationships is its status as one of the most painful experiences in life (Gordon & Mitchell, 2020). Infidelity can have detrimental effects on the psychological well-being of both partners, one of which is internalized shame. Internalized shame in the context of marital infidelity arises from conflicts between personal values and fears of legal and social consequences, along with psychological impacts such as grief and fear. Internalized shame is one of the most significant types of negative and self-conscious emotional experiences, associated with withdrawal tendencies, self-control struggles, and self-disgust (e.g., self-hatred), which can influence an individual's cognitive and emotional self-assessment and overall functioning (Mensinger, 2022). This distressing emotion is characterized by inward-directed hostility and is accompanied by feelings of humiliation, inferiority, and worthlessness. It is further defined by a set of depressive emotions, including hopelessness, foolishness, and the desire to withdraw from others due to fear of rejection (Snoek et al., 2021).

Additionally, research suggests that marital disaffection in couples following infidelity may result from the erosion of trust and communication. Marriages affected by infidelity often experience increased concerns, communication crises, and diminished emotional intimacy. Marital disaffection refers to the gradual decline in emotional attachment between spouses, leading to feelings of alienation, disinterest, and indifference toward each other. This shift

replaces positive emotions with negative ones, which, in its extreme form, can lead to the dissolution of the relationship (Karasu & Ayar, 2021). In general, when romantic expectations are not met, frustration and disaffection are often directly attributed to one's spouse, resulting in diminished love and commitment. Marital disaffection occurs when couples expect their love and emotional connections to bring meaning to their lives, yet despite their efforts, this meaning fails to materialize (Prandstetter et al., 2022).

Furthermore, one of the most significant family and social consequences of infidelity is the increased inclination toward divorce. Experts believe that the inclination toward divorce typically follows a predictable trajectory, starting with minor disagreements that become persistent and increasingly serious. This pattern often leads to detachment, prolonged conflicts, dissatisfaction with marital life, and exhaustion from ongoing disputes, ultimately culminating in separation (Frye-Cox et al., 2021). Divorce is perceived as a psychological mechanism that becomes relevant when spouses feel that their marriage has turned into a threat to their well-being (Jeong et al., 2024). The inclination toward divorce increases psychological stress for both spouses, exacerbates conflicts and problems, and makes one or both partners more vulnerable and emotionally unstable. This instability can be detrimental to both partners, making it difficult for them to coexist and further complicating their ability to sustain their relationship (Kara, 2024; Masruroh et al., 2024). The consequences of divorce inclination can negatively impact various aspects of an individual's quality of life, including personal well-being, family relationships, social interactions, physical health, and economic stability (Donner, 2019).

In this regard, mindfulness-based cognitive therapy (MBCT), as one of the modern and effective therapeutic approaches, has gained significant attention in recent years, demonstrating promising outcomes in treating various groups of individuals. This approach, initially developed for managing chronic pain, improving physical functioning, and enhancing psychological well-being, is based on cultivating moment-to-moment awareness of one's experiences. MBCT helps individuals accept their experiences without preconceptions or cognitive distortions, allowing them to perceive reality without bias (Safari Dizaj et al., 2023). By fostering present-moment awareness and enabling individuals to process experiences without automatic cognitive and emotional reactions, MBCT empowers individuals to manage stress, anxiety, and other emotional

disturbances, thereby improving their mental health (Abotalebi et al., 2022). This therapeutic approach equips individuals with skills to mindfully observe their bodily sensations, thoughts, and emotions, responding in ways that reduce stress and anxiety. MBCT encourages individuals to adopt mindfulness exercises and maintain present-moment awareness, enabling them to make more effective decisions and responses to life's challenges. These practices not only support psychological well-being but also facilitate better coping mechanisms for managing high-stress situations (Cohen et al., 2007).

Given the existing research gap, the present study seeks to answer the following question: Does mindfulness-based cognitive therapy have an impact on internalized shame, marital disaffection, and inclination toward divorce in couples experiencing infidelity?

2. Methods

2.1. Study Design and Participants

This study was conducted using a quasi-experimental design with a pre-test and post-test and a control group. In terms of purpose, this research is classified as an applied study. The research design included an experimental group and a control group, both of which completed pre-test and post-test assessments.

The statistical population of this study comprised all couples who, due to experiencing infidelity by their spouses, referred to licensed counseling and psychotherapy centers affiliated with the Iranian Psychological and Counseling Organization, the State Welfare Organization, or psychiatrists licensed by the Iranian Medical Council (Anis Andisheh Clinic) in District 3 of Tehran, during the first quarter of 2024. Given that experimental studies recommend a minimum sample size of 15 participants per group (Cohen et al., 2007), this study included 16 participants in each group, resulting in a total sample of 32 individuals (8 women and 8 men). The sample was selected through convenience sampling, considering inclusion and exclusion criteria, and was randomly assigned to the experimental and control groups using a lottery method.

Inclusion criteria for participation in the study included a minimum education level of a high school diploma, no history of diagnosed psychiatric disorders or hospitalization in psychiatric institutions, no current use of psychiatric medications, an age range of 18 to 50 years, and providing informed consent for participation.

Exclusion criteria included a history of debilitating physical illnesses or diagnosed psychiatric disorders, substance abuse, alcohol dependence, or the use of psychoactive drugs, withdrawal from the study, simultaneous participation in other psychotherapy or psychological intervention programs, incomplete pre-test questionnaire responses, and absence from more than two intervention sessions.

All ethical considerations were observed in this study, including obtaining research approval from the university's research department and ethical clearance from the ethics committee.

2.2. Measures

2.2.1. Internalized Shame

This scale, developed by Cook (1993), consists of 30 items. Responses are scored on a 5-point Likert scale (0 = Never, 1 = Very Rarely, 2 = Sometimes, 3 = Often, 4 = Always). The scoring is reversed, meaning higher scores indicate higher levels of worthlessness, incompetence, inferiority, emptiness, and loneliness, while lower scores reflect higher self-confidence. Cook (1993) confirmed the validity of the questionnaire through factor analysis and reported a Cronbach's alpha reliability coefficient ranging from 0.90 to 0.94. Concurrent validity was also established by comparing the scale with happiness and co-dependency questionnaires, yielding correlations between 0.61 and 0.79. Additionally, Rajabi and Abbasi (2011) reported a content validity index (CVI) of above 0.70. The Cronbach's alpha coefficients reported for internalized shame in their study were 0.90 for the overall sample, 0.89 for men, and 0.91 for women (Rajabi & Abbasi, 2011). In the present study, the Cronbach's alpha reliability coefficient was calculated as 0.85.

2.2.2. Marital Disaffection

The Marital Disaffection Scale, developed by Kayser (1993), assesses levels of disaffection or absence of emotional connection with one's spouse and consists of 21 items. The total score ranges from 21 to 84 and is rated on a multiple-choice Likert scale (1 = Incorrect, 2 = Somewhat Incorrect, 3 = Somewhat Correct, 4 = Very Correct). In this study, the mean score was 44.7, with a standard deviation of 9.21. Higher-than-average scores indicate high levels of marital disaffection. Items 1, 3, 5, 6, 7, 8, 9, 11, 14, 16, and 21 are reverse-scored. Kayser (1993) reported a Cronbach's

alpha reliability coefficient of 0.97 for this scale (Kayser, 1993). In a study conducted by Koochi et al. (2009), the overall Cronbach's alpha coefficient for the scale was 0.88, and its content validity was confirmed by five counseling experts from the University of Isfahan (Koochi et al., 2009).

2.2.3. *Inclination Toward Divorce*

This questionnaire, designed by Rusbult et al. (1986), consists of 14 items and is used to assess individuals who are prone to divorce. Each item is rated on a 7-point Likert scale (1 = Never, 2 = Rarely, 3 = Very Little, 4 = Little, 5 = A Lot, 6 = Very Much, 7 = Always), with the total score obtained by summing the item scores. Higher scores indicate a stronger inclination toward divorce. Rusbult and Buunk (1986) reported a Cronbach's alpha coefficient ranging from 0.63 to 0.91 (Rusbult et al., 1986). The scale was standardized in Iran by Davoodi et al. (2011) on a sample of 40 couples, and its reliability was assessed using Cronbach's alpha, yielding a coefficient of 0.88 (Davoodi et al., 2011).

2.3. *Intervention*

2.3.1. *Mindfulness-Based Cognitive Therapy*

The mindfulness-based cognitive therapy intervention was conducted over eight weeks, with two-hour sessions based on the MBCT protocol developed by Crane. Before the intervention, an introductory session was held to familiarize participants with the program and conduct preliminary assessments. A structured homework plan was also included, requiring 45 minutes of daily practice, consisting of formal mindfulness exercises and, on some days, informal mindfulness practices, along with self-observation logs.

Session 1: Automatic functioning – Practical exercises focusing on performing simple tasks with awareness, session exercises, and homework assignments.

Sessions 2 and 3: Staying in the moment – Awareness of breathing, body sensations, sounds, thoughts, and mindful decision-making.

Session 4: Continued practice of staying in the moment – Further awareness of breathing, body sensations, sounds, thoughts, and mindful choices.

Session 5: Acceptance and allowing – Incorporation of meditation sessions.

Session 6: Thoughts do not represent reality – Identifying the impact of negative thoughts on the body and mind

through exercises, including a three-minute breathing space practice.

Session 7: Self-care strategies – Meditation sessions focusing on breath awareness, body sensations, sounds, thoughts, and emotions.

Session 8: Integrating mindfulness into future decision-making – Body scan meditation and conclusion of the intervention.

2.4. *Data Analysis*

The collected data were analyzed using both descriptive and inferential statistics. At the descriptive level, frequency, percentage, mean, and standard deviation were calculated to quantify the research findings. At the inferential level, the Shapiro-Wilk test was used to assess the normality of the research variables. Subsequently, multivariate analysis of covariance (MANCOVA) and univariate analysis of covariance (ANCOVA) were used to test the research hypotheses. These statistical methods were employed to evaluate the effects of independent variables on dependent variables while controlling for other influencing factors. All statistical analyses were conducted using SPSS version 23.

3. *Findings and Results*

The study sample consisted of 32 participants (16 in the control group and 16 in the experimental group), including 16 women and 16 men. Participants' ages ranged from 18 to 40 years.

In the control group, 5 participants had a high school diploma, 8 had a bachelor's degree, 2 had a master's degree, and 1 held a doctoral degree. Among the 8 women in the control group, 1 had a high school diploma, 5 had a bachelor's degree, 1 had a master's degree, and 1 had a doctoral degree. Among the 8 men in the control group, 4 had a high school diploma, 3 had a bachelor's degree, and 1 had a master's degree.

In the experimental group, 2 participants had a high school diploma, 4 had an associate's degree, 9 had a bachelor's degree, and 1 had a doctoral degree. Among the 8 women in the experimental group, 2 had an associate's degree, and 6 had a bachelor's degree. Among the 8 men in the experimental group, 2 had a high school diploma, 2 had an associate's degree, 3 had a bachelor's degree, and 1 had a doctoral degree.

Table 1 presents the mean and standard deviation of marital disaffection, internalized shame, and inclination

toward divorce scores in the pre-test and post-test for the control and experimental groups.

Table 1

Descriptive Statistics of Marital Disaffection, Inclination Toward Divorce, and Internalized Shame in Pre-Test and Post-Test for the Control and Experimental Groups

Variable	Test Phase	Sample Size	Control Group M (SD)	Experimental Group M (SD)
Marital Disaffection	Pre-Test	16	68.19 (5.59)	53.69 (2.09)
	Post-Test	16	70.50 (5.33)	47.19 (2.84)
Attachment	Pre-Test	16	28.38 (2.81)	26.50 (1.83)
	Post-Test	16	29.19 (2.81)	21.82 (2.17)
Emotional Alienation	Pre-Test	16	23.32 (2.06)	21.63 (1.09)
	Post-Test	16	23.94 (2.21)	14.57 (1.64)
Emotional Support	Pre-Test	16	16.50 (1.60)	15.57 (1.21)
	Post-Test	16	17.38 (1.21)	11.44 (2.07)
Inclination Toward Divorce	Pre-Test	16	71.44 (5.21)	67.75 (2.49)
	Post-Test	16	72.19 (4.81)	51.82 (2.66)
Internalized Shame	Pre-Test	16	115.00 (13.59)	107.13 (3.65)
	Post-Test	16	117.75 (13.34)	66.32 (3.33)
Self-Esteem	Pre-Test	16	33.63 (2.42)	30.63 (1.41)
	Post-Test	16	34.44 (1.72)	24.19 (2.05)
Shyness	Pre-Test	16	81.38 (12.20)	77.13 (3.82)
	Post-Test	16	83.69 (11.98)	42.13 (2.58)

To assess the significance of differences in the combined mean scores of internalized shame, marital disaffection, and inclination toward divorce, a multivariate analysis of variance (MANOVA) was conducted using Wilks' Lambda. Wilks' Lambda, alongside Pillai's trace, Hotelling's trace, and Roy's largest root, is one of the multivariate tests that determine whether a statistically significant difference exists between the groups in the linear combination of the dependent variables.

The Pillai's trace value was 0.877, and the obtained F-value was 59.377, with a significance level of $p < 0.01$, and

degrees of freedom (3, 25). This indicates a statistically significant difference between the control and experimental groups in at least one of the variables: internalized shame, marital disaffection, or inclination toward divorce.

Based on the effect size ($\eta^2 = 0.88$), mindfulness-based cognitive therapy (MBCT) had a significant effect on internalized shame, marital disaffection, and inclination toward divorce among couples who had experienced infidelity ($\Lambda = 0.877, F(3, 25) = 59.377, p < 0.01, \eta^2 = 0.88$).

Table 2

ANCOVA Results for Differences in Marital Disaffection, Inclination Toward Divorce, and Internalized Shame

Variable	Source	SS	df	MS	F	Sig.	Effect Size (η^2)
Marital Disaffection	Group	3034.510	1	3034.510	162.34	0.001	0.86
Inclination Toward Divorce	Group	2420.035	1	2420.035	53.77	0.001	0.67
Internalized Shame	Group	14496.810	1	14496.810	148.91	0.001	0.85
Marital Disaffection	Error	504.708	27	18.693	-	-	-
Inclination Toward Divorce	Error	1215.140	27	45.005	-	-	-
Internalized Shame	Error	2628.622	27	97.356	-	-	-
Marital Disaffection	Total Adjusted	4894.219	-	-	-	-	-
Inclination Toward Divorce	Total Adjusted	4546.000	-	-	-	-	-
Internalized Shame	Total Adjusted	23998.969	-	-	-	-	-

The results in Table 2 indicate that the obtained F-value for marital disaffection was 162.34, with a significance level

of $p = 0.001$, which is less than the 0.01 threshold. Thus, MBCT significantly reduced marital disaffection in couples

who had experienced infidelity by 0.86 units ($F(1,27) = 162.34, p < 0.01, \eta^2 = 0.86$).

Similarly, the F-value for inclination toward divorce was 53.77, with a significance level of $p = 0.001$, which is less than 0.01. Therefore, MBCT significantly reduced inclination toward divorce in couples who had experienced infidelity by 0.67 units ($F(1,27) = 53.77, p < 0.01, \eta^2 = 0.67$).

Furthermore, the F-value for internalized shame was 148.91, with a significance level of $p = 0.001$, which is less

than 0.01. Consequently, MBCT significantly reduced internalized shame in couples who had experienced infidelity by 0.85 units ($F(1,27) = 148.91, p < 0.01, \eta^2 = 0.85$).

To examine the adjusted means in both the control and experimental groups, the following table presents the adjusted mean scores.

Table 3

Adjusted Mean Scores for Marital Disaffection, Inclination Toward Divorce, and Internalized Shame

Index	Group	Marital Disaffection	Inclination Toward Divorce	Internalized Shame
Mean	Control	70.35	72.27	117.17
	Experimental	47.35	51.74	66.90
S.E	Control	1.183	1.835	2.699
	Experimental	1.183	1.835	2.699

According to [Table 3](#), the adjusted mean scores for marital disaffection (47.35 vs. 70.35), inclination toward divorce (51.74 vs. 72.27), and internalized shame (66.90 vs. 117.17) were lower in the experimental group compared to the control group. This indicates that mindfulness-based cognitive therapy (MBCT) had a significant effect on reducing marital disaffection, inclination toward divorce, and internalized shame in couples who had experienced infidelity.

4. Discussion and Conclusion

The present study aimed to examine the effectiveness of mindfulness-based cognitive therapy (MBCT) on internalized shame, marital disaffection, and inclination toward divorce in couples who had experienced infidelity. The results demonstrated that MBCT had a significant impact on reducing these variables. The findings were consistent with previous studies and indicated that MBCT effectively enhances psychological well-being and marital relationships. This finding is consistent with the results of prior studies ([Alizadeh & Mohammadi, 2021](#); [Homayouni et al., 2023](#); [Proeve et al., 2018](#); [Styne et al., 2022](#)).

In this regard, MBCT can serve as an effective intervention for reducing internalized shame. This therapeutic approach provides a space for self-awareness and non-judgmental acceptance of experiences, helping individuals detach from the negative cycle of thoughts and emotions associated with internalized shame. In particular, for couples who have experienced infidelity, MBCT can aid in improving their relationship with themselves and others

while reducing negative emotions such as shyness and low self-esteem. Psychological theories suggest that internalized shame is often associated with negative and generalized self-evaluations, which can lead to decreased self-esteem and increased feelings of incompetence ([Ahmadpour, 2021](#)). In this context, MBCT, by focusing on self-acceptance and present experiences, can help reduce these negative self-evaluations and enhance self-esteem.

Therefore, mindfulness exercises can assist individuals in establishing a better connection with their bodies, thoughts, and emotions, leading to a greater understanding of themselves and their experiences. MBCT, through training in self-awareness and acceptance techniques, can reduce concerns and increase self-confidence. This method allows individuals to distance themselves from self-critical negative thoughts and build better relationships with themselves and others. Given that marital infidelity typically results in diminished trust and increased negative emotions such as shame and shyness, MBCT fosters acceptance and self-awareness, enabling couples to break free from the negative cycle of thoughts and emotions associated with infidelity and establish more positive interactions.

The findings also showed that MBCT had a significant effect on marital disaffection in couples who had experienced infidelity, reducing disaffection by 0.86 units ($p < .01$). This intervention significantly decreased the components of marital disaffection, including emotional detachment, emotional alienation, and emotional support. This finding aligns with prior findings ([Hosseini, 2023](#)).

In explaining this result, it can be stated that marital disaffection is a gradual and complex process that arises from various factors, including a mismatch between individual expectations and the realities of married life (Mokhtari et al., 2021). Marital disaffection refers to feelings of disillusionment and frustration resulting from the failure to fulfill emotional expectations and needs, which can lead to a gradual decline in emotional attachment and an increase in emotional alienation. MBCT, as a therapeutic method that focuses on mindfulness exercises and present-moment awareness, can effectively reduce marital disaffection.

This approach enhances mindful attention and acceptance skills, helping individuals to face the realities of their married life more realistically and distance themselves from irrational attachments and unrealistic expectations. By using MBCT, individuals can continuously redirect their focus to their present emotional state, allowing them to experience moments without negative and judgmental perceptions. These mindfulness exercises help couples gain a better understanding of their own and their partner's needs, promoting a more balanced and empathetic approach to their relationship. Consequently, present-moment awareness and non-judgmental acceptance can lead to a reduction in emotional alienation and an increase in emotional support within marital relationships.

The results also indicated that MBCT had a significant effect on reducing inclination toward divorce in couples who had experienced infidelity, decreasing it by 0.69 units ($p < .01$). This finding is consistent with prior research (Ghaedi et al., 2022; Mokhtari et al., 2021; Roberts et al., 2020).

In explaining this finding, MBCT has been widely used as an intervention to help couples who have experienced infidelity in reducing their inclination toward divorce. By employing techniques of present-moment awareness and non-judgmental acceptance, MBCT enables couples to minimize the negative effects of infidelity on their marital relationship and work toward repair and restoration.

The primary goal of MBCT is to strengthen mindfulness skills, allowing individuals to approach their issues with greater acceptance and self-awareness and distance themselves from negative thoughts and hasty judgments. One of the most significant consequences of infidelity is an increased inclination toward divorce (Ghasemzad, 2020). Infidelity often triggers emotional and psychological crises in couples. When infidelity occurs, feelings of betrayal, disappointment, and hopelessness in the relationship frequently act as triggers for the decision to divorce. Marital

infidelity damages trust, and when a partner feels unable to rebuild trust, the desire to end the relationship intensifies.

In this context, MBCT is designed to help couples focus on present realities rather than dwelling on negative emotions and past events (Roberts et al., 2020). This process includes acceptance of past experiences rather than attempting to suppress or escape them, thereby reducing negative emotions and enhancing psychological resilience. For instance, during therapy sessions, individuals are encouraged to fully experience their emotions without judgment, a practice that can significantly reduce stress and improve coping abilities. These findings highlight the importance of mindfulness-based therapeutic approaches in improving marital relationships and mitigating the psychological damage caused by infidelity.

5. Suggestions and Limitations

However, the study had several limitations, including inability to fully control environmental and familial variables affecting participating couples, use of self-report instruments to measure internalized shame, marital disaffection, and inclination toward divorce, time constraints for conducting MBCT sessions and data collection, and lack of a follow-up phase.

Based on these findings, the following recommendations are proposed:

Counseling and therapy centers should implement structured MBCT programs for couples dealing with infidelity.

Couples should participate in both individual and group counseling sessions to enhance their communication and support skills.

Couples should incorporate mindfulness techniques into their daily lives to manage conflicts and challenges with a more conscious and balanced approach.

Future research should explore the long-term effects of MBCT on couples experiencing infidelity, aiming to identify and develop more effective methods for improving psychological and marital well-being.

Future studies should employ experimental designs with greater control over environmental and familial variables affecting couples.

Qualitative research methods, such as in-depth interviews and direct observations, should be used to gain a deeper understanding of the real effects of these variables.

Authors' Contributions

All authors have contributed significantly to the research process and the development of the manuscript.

Declaration

In order to correct and improve the academic writing of our paper, we have used the language model ChatGPT.

Transparency Statement

Data are available for research purposes upon reasonable request to the corresponding author.

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Declaration of Interest

The authors report no conflict of interest.

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Ethical Considerations

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

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