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# The effect of digital coloring on the level of state anxiety and pulse rate in elderly patients before diabetic foot ulcer surgery: A quasi-experimental study

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# Abstract

**Background:** Given the anxiety experienced by patients awaiting diabetic foot ulcer surgery, evidence supporting the efficacy of preoperative art therapy can be clinically valuable. However, evidence on the effectiveness of digital coloring, a modern and accessible form of art therapy, remains limited. This study aimed to investigate the effects of digital coloring on state-trait anxiety levels and pulse rate in elderly patients scheduled for diabetic foot ulcer surgery.

**Methods:** This quasi-experimental study employed a pre-test-post-test design with intervention and control groups. The study was conducted from January 2023 to July 2024 at a referral teaching hospital in Amol, Iran. The participants were selectively assigned to either an intervention group (n=30) or a control group (n=30) via purposive sampling. Both groups received standard preoperative care, but one hour before the scheduled surgery, the intervention group received a one-session digital coloring. Data were collected using a demographic questionnaire and the State-Trait Anxiety Inventory (STAI form Y-1). The variables were assessed at baseline and immediately after the coloring session in both study groups. An analysis of covariance (ANCOVA) was conducted to compare post-intervention state anxiety between the intervention and control groups, while controlling for pre-intervention anxiety levels. Data analysis in SPSS v25 employed  $\chi^2$ , Fisher's exact, paired, and independent t-tests, with significance set at p<0.05.

**Results:** Both study groups were homogeneous in terms of gender, age, and education level. Baseline anxiety (p=0.43) and pulse rate (p=0.12) were similar between groups. Post-intervention results revealed a clinically meaningful reduction in the intervention group ( $43.20\pm3.70$ ) versus controls ( $50.33\pm6.18$ ), with a significant between-group difference (p<0.001, d=1.42). The between-group difference in pulse rate was also significant (p=0.002), with a large effect size (Cohen's d=0.87).

**Conclusion**: Our findings suggest that the digital coloring intervention may be associated with reductions in state anxiety and pulse rate among elderly patients awaiting diabetic foot ulcer surgery. Given that this intervention is simple, inexpensive, and easily accessible, we recommend its use to alleviate state anxiety in clinical settings that typically provoke anxiety, such as during diagnostic procedures.

# Article Type: Research Article

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# Keywords

Anxiety Diabetic foot Aged Art therapy Surgical procedures



# Highlights

#### What is current knowledge?

Current knowledge highlights that patients awaiting diabetic foot ulcer surgery often experience high levels of anxiety, which can negatively impact their recovery and surgical outcomes. Non-pharmacological interventions, such as art therapy, have been explored as potential methods to reduce anxiety, with traditional coloring showing some benefits. However, evidence on the effectiveness of digital coloring, a modern and accessible form of art therapy, remains limited, particularly in adult populations undergoing high-stress medical procedures.

#### What is new here?

This study introduces digital coloring as a novel, simple, and cost-effective intervention to reduce state anxiety and heart rate in patients awaiting diabetic foot ulcer surgery. The results demonstrate significant reductions in anxiety and physiological stress markers post-intervention, highlighting the potential of digital tools in clinical settings. This approach offers a scalable and easily implementable solution to improve preoperative patient well-being, addressing a gap in current non-pharmacological anxiety management strategies.

# Introduction

The prevalence of diabetes has increased globally, and this disease has become a serious and chronic metabolic disease worldwide (1). In Asia, the Middle East and North Africa, this increase is more impressive than in other parts of the world (2). In this context, based on recent epidemiological studies in Iran, in addition to the increasing prevalence of diabetes, the prevalence of this disease has been estimated to be >10% of the total population of the country, which is a high level compared to the global prevalence (3,4).

Diabetes is one of the diseases that brings many complications over the years and the prevalence of complications such as ulcers, cardiovascular diseases, retinopathy, neuropathy and nephropathy is high in these patients (5). Diabetic foot ulcers are a serious complication in this group of patients, affecting around 18.6 million people worldwide each year, and are associated with an increased rate of amputation and death (6,7). Surgical debridement, weight-bearing decompression, treatment of lower limb ischemia and foot infections, and early referral to Specialty Medical Centers are the first line of treatment for diabetic foot ulcers (8,9). Diabetic foot ulcer is one of the most common causes of hospitalization of diabetics in Iran, and the rate of diabetic foot ulcers with subsequent amputation is 30.6% in Iranian hospitals (10,11). Diabetic foot ulcers affect the physical and psychological quality of life of these people and they suffer from constant anxiety due to the fear of infection, spreading of the wound and amputation (12,13). The level of

state-trait anxiety before surgeries related to diabetic foot increases in patients due to the possibility of amputation and the discovery of a large wound during surgery (14).

A systematic review study in 2020 has indicated that diabetics with diabetic ulcers experience high levels of anxiety, stress, and depression (15). At the same time, the results of the studies represent that anxiety can slow down the wound healing process in these people (16). As this group of patients suffers from severe anxiety before surgery, they are usually given medication before surgery to combat the anxiety (17). However, the use of anti-anxiety and sedative medications before surgery is associated with various adverse effects, including respiratory depression, confusion, delirium, risk of falls, drowsiness, cardiac arrhythmias, and changes in blood pressure. These effects are exacerbated in elderly patients due to impaired liver and kidney function, as well as drug interactions (18,19). It is therefore recommended to take non-pharmacological measures to control their anxiety as much as possible (20). One of the methods to control anxiety is an art therapy that acts on the center of anxiety, emotions, and stress in the brain (Amygdala area) and somehow leads to relaxation of this area of the brain (21,22).

Several studies have pointed to the benefits of art therapy in reducing anxiety and positive changes in people's mood (23,24). According to the studies, art therapy seems to create a stable state and reduce anxiety by creating alpha waves and reducing beta waves in the brain (25-27). One of the methods of art therapy is coloring, which comes in various forms (28). One of the new coloring methods that is becoming increasingly popular today is digital coloring, which comes in a wide range from very professional to simple levels with various applications (29). Previous studies have demonstrated that coloring activities can significantly reduce anxiety levels, neurophysiological evidence supporting its therapeutic effects (30,31). Functional neuroimaging studies have revealed that engaging in structured coloring tasks modulates activity in the amygdala, the brain's primary stress-processing center, while simultaneously enhancing prefrontal cortex activation associated with emotional regulation (32,33). These findings suggest that coloring induces a meditative state, similar to mindfulness practices, by shifting neural activity from stressrelated pathways to regions involved in focused attention and relaxation. Furthermore, psychometric assessments have consistently reported decreased cortisol levels and improved subjective well-being following coloring interventions (31). However, the number of studies that have investigated the effect of digital coloring therapy, especially in elderly patients, is limited. According to the researchers' search, the effectiveness of this digital coloring therapy on state-trait anxiety and

pulse rates in the patients before diabetic foot ulcer surgery has not yet been studied. Therefore, the present study aimed to evaluate the effectiveness of digital coloring therapy in reducing state-trait anxiety levels and pulse rate among elderly patients awaiting diabetic foot ulcer surgery.

### Methods

#### Study design

This quasi-experimental study employed a pre-test and post-test design with control and intervention groups to investigate the effect of digital coloring on state anxiety levels and pulse rate in elderly patients awaiting diabetic foot ulcer surgery.

## Setting and participants

The study was conducted from January 2023 to July 2024 at Imam Reza referral teaching hospital in Amol, northern Iran. This hospital is one of the leading centers in Mazandaran province for the surgical treatment of diabetic foot ulcers. The study sample was elderly patients awaiting diabetic foot ulcer surgery, referred to this hospital. Inclusion criteria included age ≥60 years, awareness of time and place, having grade 3 or higher diabetic foot ulcers according to the Wagner Classification System use of a tablet or smartphone in the past, absence of visual impairment leading to color impairment, absence of impairment of the dominant hand to hold a digital pen, and no previous experience with diabetic foot surgery, no consumption of sedative or anti-anxiety medications and no medical history of psychiatric or stress-related disorders. Individuals were excluded if they did not wish to participate and continue in the study. In the current study, no participant expressed unwillingness to continue in the study and was not excluded from the study samples (Figure 1). The participants were non-randomly allocated via purposive sampling into two 30-person groups: intervention and control. To avoid information bias and direct contact between the samples in two groups, subjects with odd admission day numbers were first assigned to the control group and subjects with even admission day numbers to the intervention group. Subsequently, the subjects were selected by purposive sampling. The sample size was calculated based on pilot data from 20 patients awaiting diabetic foot ulcer surgery (10 per group), which showed a mean reduction of seven points in anxiety scores (SD=5.5) in the intervention group compared to 1 point (SD=6) in the control group. Using an effect size of d=0.8 (to ensure conservatism), a power of 90%, and α=0.05, G\*Power software indicated a requirement of 26 participants per group. Accounting for a 10% attrition rate, the final sample size was set to 30 participants per group (Total N=60).

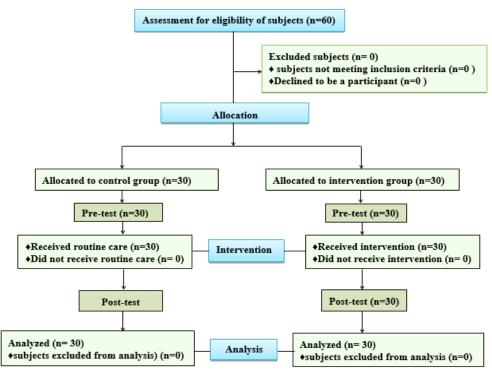


Figure 1. Flow chart of the study design

#### Instruments

Demographic information was gathered through the use of an anonymous questionnaire. The anxiety levels of the study participants were assessed utilizing the State-Trait Anxiety Inventory (STAI form Y-1). The STAI form Y-1 is a self-assessment questionnaire and a standard that is widely recognized as a standard instrument for assessing statetrait anxiety. Additionally, it is applicable in clinical settings to diagnose anxiety. It comprises 20 items. All items of the STAI are rated on a 4point scale from "1 = almost never" to "4 = almost always". Higher scores indicate a higher level of anxiety (from 20 to 80). STAI scores are classified as follows: "no or low anxiety" (20-37), "moderate anxiety" (38-44), and "high anxiety" (45-80). This questionnaire has been widely utilized as a valid and reliable tool in various studies across diverse populations (34,35) in Iran. A validation study conducted in Iran evaluated the psychometric properties of the Persian version of STAI form Y-1. The study reported that its Cronbach's alpha and test-retest correlation coefficients were 0.846 (36). All questionnaires were completed by the study's investigator (First author) to ensure consistency in data collection procedures.

The patients' radial pulse was measured for one minute while they were lying supine on the bed. Pulse counting was performed under the following preconditions: no physical activity, no smoking or coffee consumption, and absence of all other stimulants known to increase pulse rate for at least 20 minutes prior to measurement (19). Pulse rate measurements were taken twice -both before and after the interventionprior to questionnaire completion by the study's investigator (First author).

#### **Procedure**

The study protocol ensured that all participants were fully informed about the research objectives prior to the study commencement. Written informed consent was obtained from those who agreed to participate. For all patients, the intervention began one hour before the surgery. Baseline measurements, including state-trait anxiety scores and pulse rates, were recorded for both the control and intervention groups. All participants' radial pulses were measured for one minute in a seated position on the hospital bed using a stopwatch. All patients maintained a resting state for ≥30 minutes prior to pulse evaluation, with no tobacco consumption, caffeine intake, or excessive physical exertion during this period. In the intervention group, participants engaged in a coloring activity following the researcher's instructions. They were asked to color three simple nature-themed motifs (e.g., flowers or landscapes, selected for adult appropriateness) using a coloring application on a 2019 Samsung Galaxy Tab A 8.0 (10-inch display) (37). It should be noted that coloring in this method is very simple since the color and the place of coloring are fixed. Moreover, the person completes the coloring by simply touching the designated areas with the digital pen. The coloring session duration ranged from 20 to 25 minutes (38). Finally, the anxiety levels and pulse rates in the intervention group were assessed once more ten minutes following the intervention. The control group received standard preoperative care at hospital, which included only essential medical procedures: administration of prescribed medications (e.g., antibiotics or anticoagulants if needed), notification of surgery timing, and changing into surgical attire. No additional relaxation activities (e.g., conversations with nurses, TV access, or other nonpharmacological interventions) were provided, as these are not part of routine care in the surgical unit. It should be noted that after each intervention, the tablets and pens were disinfected and then used for the next participant. Although blinding was impossible due to the nature of the intervention, data analysis was performed by a statistician blinded to group allocation to ensure objectivity in outcome assessment.

# Statistical analysis

Descriptive and inferential analyses were performed using IBM SPSS Statistics 25 (Armonk, NY: IBM Corp). Group homogeneity was assessed via  $\chi^2$  tests (For categorical variables), Fisher's exact tests (Where cell counts<5), and independent t-tests (For continuous variables). Between-group comparisons of State Anxiety and pulse rate were analyzed using independent t-tests. Cohen's d was used to calculate the effect size, quantifying the standardized magnitude of the difference between group means. It was calculated using the pooled standard deviation for between-group comparisons and the standard deviation of the gain scores for within-group comparisons (Interpreted as: 0.2 = small, 0.5 = medium, 0.8 = large). Also, 95% confidence intervals (CIs)

for mean differences were reported. Within-group comparisons were conducted using paired t-tests, similarly reporting Cohen's d and 95% CIs for pre-post intervention changes. For categorical outcomes (Anxiety levels),  $\chi^2$  tests were supplemented for proportion differences. All tests were two-tailed with  $\alpha = 0.05$ , with statistical significance interpreted alongside effect sizes.

## Results

The statistical results illustrated that the study samples in both groups had no statistically significant differences in terms of demographic characteristics. Half of the study subjects were female and more than half of the study subjects were married (58.35%), had a primary school degree (73.35%). The mean and standard deviation of the age of the study samples were  $69.75 \pm 4.22$  (Table 1).

**Table 1.** Baseline characteristics of elderly patients scheduled for diabetic foot ulcer surgery in the intervention and control groups

Characteristics, Total (n=60)	Control group N=30	Intervention group N=30	Statistic test and p-value	
Age, (Years) (Mean ± SD)	$70.03 \pm 4.07$	69.47 ± 4.41	t = 0.51, p*= 0.607	
Male	11 (36.7)	15 (50)	$x^2 = 1.08 p^{**} = 0.298$	
Female	19 (63.3)	15 (50)		
Ed				
Primary	23 (76.7)	21 (70)	p***= 0.721	
Secondary	6 (20)	8 (26.7)		
High school and diploma	1 (3.3)	1 (3.3)		

p\*: Independent sample t-test. p\*\*: Chi-square test p\*\*\*: Fisher's Exact Test

For state anxiety outcome, while no baseline difference existed between groups (control: 48.66±6.05 vs intervention: 49.93±6.53; p=0.43, d=0.20), post-intervention results revealed a clinically meaningful reduction in the intervention group (43.20±3.70) versus controls (50.33±6.18), with a significant between-group difference of -7.13 points (p <0.001, d=1.42, large effect). The proportion of high anxiety cases decreased from 83.3% to 23.3% in the intervention group (p <0.001), compared to 86.7% remaining high anxiety in controls. within-group analyses revealed a significant 6.73-point reduction in the intervention group (49.93 to 43.20; p<0.001, d=1.30) and 1.67-point increase in controls (48.66 to 50.33; p=0.007, d=0.27) (Table 2).

Levene's test confirmed homogeneity of variances (F=0.035, p=0.853). The ANCOVA revealed a statistically significant effect of the intervention on post-intervention anxiety after adjusting for baseline anxiety, F=51.72, p<0.001, partial  $\eta$ 2=0.476, indicating a large effect size. Pre-intervention anxiety also significantly predicted postintervention anxiety, F=22.53, p<0.001, partial  $\eta$ 2=0.283. The model explained 54.3% of the variance in post-intervention anxiety  $(R^2=0.543)$ .

Pulse rate measurements showed parallel improvements. From comparable baselines (control: 79.20±1.86 vs intervention: 80.20±2.98; p=0.125, d=0.40), the intervention group achieved a significant 5.60 bpm reduction (p<0.001) versus a 0.87 bpm increase in controls, yielding a between-group difference of -5.47 bpm (p=0.002, d=0.87, large effect). Within-group analyses revealed that the intervention group showed a significant 5.60 bpm reduction (from 80.20±2.98 to 74.60±8.39; p<0.001, d=0.85), while the control group demonstrated a non-significant 0.87 bpm increase (From 79.20±1.86 to 80.07±3.94; p=0.317, d=0.26), indicating a clinically significant improvement in the intervention group compared to controls (Table 2).

 Table 2. Comparison of outcomes between the control and intervention groups at baseline and after the intervention

Outcomes	Control group	Intervention group	Between-group comparison p-value, Cohen's d, MD		
Total score of state anxiety at baseline (Mean±SD)	$48.66 \pm 6.05$	$49.93 \pm 6.53$	p*= 0.43 d:0.20 MD: 1.27		
Total score of state anxiety after intervention (Mean±SD)	$50.33 \pm 6.18$	$43.20 \pm 3.70$	p*= 0.000 d:1.42 MD: -7.13		
Within-group comparison P-value, MD, Cohen's d	p**= 0.007 MD:1.566 d:0.27	p**= 0.0001 MD: -7.266 d:1.30	-		
Pulse rate at baseline (Mean±SD)	$79.20 \pm 1.86$	$80.20 \pm 2.98$	p*= 0.125 d:0.4 MD: 1		
Pulse rate after intervention (Mean±SD)	$80.07 \pm 3.94$	$74.60 \pm 8.39$	p*= 0.002 d:0.87 MD: -5.47		
Within-group comparison p-value, MD, Cohen's d	p**= 0.317 MD:0.867 d:0.26	p**= 0.0001 MD: -5.60 d:0.85	-		
Level of state anxiety at baseline N (%)					
Moderate anxiety (38-44)	8 (26.6)	5 (16.7)	2 0.00 *** 0.24		
High anxiety (45-80)	22 (73.7)	25 (83.3)	$x^2 = 0.88$ $p^{***} = 0.34$		
Level of state anxiety after intervention N (%)					
Moderate anxiety (38-44)	4 (13.3)	23 (76.7)	$x^2 = 24.31$ $p^{***} = 0.0001$		
High anxiety (45-80)	26 (86.7)	7 (23.3)			

p\*: Independent sample t-test

P\*\*: Paired t-test

P\*\*\*: Chi-square test

MD: Mean Difference

#### Discussion

This study investigated the impact of digital coloring on situational anxiety and pulse rates among elderly patients before diabetic foot ulcer surgery. The results indicated that this intervention was effective in reducing anxiety and pulse rate.

In the current study, the intervention and control groups had similar characteristics in terms of demographic variables such as age, gender, marital status, educational and economic status, and variables of state anxiety, pulse rate, and there were no significant statistical differences. It is important that the study groups have similar characteristics in order to evaluate the effectiveness of the intervention, and in this study, the two groups were homogeneous. In the current study, pre-intervention anxiety levels were high in both groups. This result is consistent with the results of the studies that have mentioned that the level of anxiety before diabetic foot surgery is high (17,39).

The findings indicated that state anxiety decreased statistically significantly after the intervention in the intervention group compared to the control group. This aligns with a 2020 study, in which the companions of patients undergoing micrographic surgery were asked to color motifs in adult coloring books. The results suggested that coloring led to a reduction in anxiety in the companions of patients. One of the reasons cited by the researchers for the effectiveness was that focusing on coloring allowed the mind to relax and let go of any problems and demands that may have led to stress (40). When people create something beautiful through drawing, they stimulate the creative mind and, at the same time, reduce mental pressure. They also mentioned in their results that this intervention was very easy to perform, with high feasibility, low cost and satisfaction of the study subjects. Therefore, they described this method as a suitable solution to reduce the anxiety of surgery (41).

These findings align with a study demonstrating that art therapy significantly improved pain, mood, and anxiety scores in patients. The researchers attributed this to art's calming effect on the nervous system, reducing sympathetic chemical levels and promoting relaxation. Given the large sample size and observed psychosocial benefits, art therapy may shorten hospital stays, enhance patient satisfaction, and reduce the need for pain medication. They concluded it is a safe, cost-effective adjunct to conventional treatment (26).

In 2023, the results showed that digital and traditional coloring led to lower levels of death anxiety compared to non-artistic activities, and the reduction in anxiety was greater in the digital coloring group than in the traditional coloring group, which may to some extent justify the effectiveness of the present study. Although Roh et al. (2023) reported superior anxiety reduction with digital coloring in older adults, our effect sizes were comparable to traditional methods. This discrepancy may reflect our stricter inclusion criteria (Excluding psychiatric comorbidities) or the acute surgical context, which differs from their non-medical setting (37). In the same field, another study aimed to determine the effectiveness of the use of art therapy (Painting) in

reducing anxiety and depression in a group of female students. Considering the positive effectiveness of the art therapy, the researchers recommended this intervention in clinical and hospital settings. They mentioned that art therapy, particularly through painting, has been noted to enhance non-verbal communication between patients and healthcare professionals. This approach not only aids in the treatment process but also contributes to an improved mood, thereby potentially decreasing the need for medication (42).

In a study examining the effectiveness of different types of coloring on stress levels, it was found that unstructured, free-form coloring had less impact on stress reduction. The researchers suggested that patterned designs function similarly to meditation for the mind (24). Contrary to these findings, several studies have reported that patterned coloring does not significantly differ from free-form coloring, with both demonstrating similar calming effects on the brain (43-45). Systematic reviews reveal inconsistent evidence regarding coloring's anxiolytic effects across demographics, highlighting the need for robust studies in diverse populations to establish therapeutic efficacy (46,47).

The intervention group exhibited a significantly lower post-intervention pulse rate than controls. Since elevated pulse rate predicts anxiety, this reduction likely reflects diminished situational anxiety. Consistent with our findings, previous studies in the field of art therapy and coloring interventions have demonstrated that coloring regulates emotional responses, promotes a balance between sympathetic and parasympathetic nervous system activity, and contributes to mood enhancement, thereby reducing anxiety and stress (29,47). Our observed pulse rate reduction extends prior art therapy research by demonstrating concurrent psychophysiological effects. However, this mirrors rather than surpasses the 4-7 bpm reductions seen in music therapy studies (32), suggesting digital coloring operates through established relaxation pathways rather than unique mechanisms.

Notably, all intervention group participants reported satisfaction and enhanced tranquility post-intervention. Given the widespread use of digital technologies and smartphones across all age groups worldwide, this intervention appears to be applicable to diverse populations and age ranges.

The strengths of this study include its status as one of the first to investigate the novel application of digital coloring as a non-pharmacological intervention for reducing preoperative anxiety, specifically within the high-stress context of diabetic foot ulcer surgery in the elderly population. The methodology is further strengthened by the use of a standardized, reliable instrument (STAI Form Y-1) to measure the primary outcome. Furthermore, the intervention was highly feasible, inexpensive, and well-accepted by participants, suggesting significant potential for implementation in real-world clinical settings.

This study also has limitations that must be acknowledged. The nonrandom allocation of participants, achieved through alternate-day assignment, was practical but introduces a potential for selection bias



and limits the strength of causal inferences. Furthermore, the intervention's nature made blinding impossible, which may have influenced subjective reporting. Finally, potential confounding variables, such as the use of pulse-rate-influencing cardiac medications (e.g., beta-blockers), were not measured or controlled for.

#### Conclusion

This study demonstrates that digital coloring effectively reduces state anxiety and pulse rates in preoperative diabetic foot ulcer patients. As a simple, cost-effective, and accessible intervention requiring minimal resources, it shows particular promise for anxiety-provoking clinical settings like diagnostic assessments. Although these findings support its clinical utility, further research should validate efficacy across diverse populations and medical procedures. Healthcare providers should consider implementing brief digital coloring sessions in preoperative protocols, potentially reducing reliance on pharmacological interventions. Future studies should investigate long-term effects, while policymakers may explore integrating such art-based therapies into standard care pathways.

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# **Ethical statement**

This study was performed in line with the principles of the Declaration of Helsinki. The Ethics Committee of Babol University of Medical Sciences approved this study to protect subjects from risks (Approval Code: IR.MUBABOL.REC.1401.045). All participants involved in the current study were made aware of the objectives and stages of the research. Confidentiality and independence were assured and informed consent was signed. The information gathered in this study was securely stored, with access limited exclusively to the researchers involved. All subjects were informed that their choice to engage in the study was entirely voluntary and would not negatively impact their medical care or standard hospital treatment. The current study prioritized participant safety. Furthermore, participants were guaranteed that their personal identifiers would not be utilized in all project-related reports and publications to safeguard their privacy. Informed consent to participate was obtained from all of the participants.

# **Conflicts of interest**

The authors declared no potential conflicts of interest.

#### **Author contributions**

Conceptualization and design: S.M, F.A, A.Sh. Funding acquisition: S.M. Data collection: S.M, F.A. Data analysis and interpretation: S.M, O.K. Drafting of the article: S.M, F.A, A.Sh. Critical revision of the article: S.M, O.K.

# Data availability statement

In order to protect the privacy of the participants, the data generated during this study will not be made public. Nevertheless, it may be accessible to the corresponding author upon reasonable request.

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